

12-16-94

Residue Chemistry Review

Comments:

Subject: PP#'s 9F3770 and 7F3560. Cyhalothrin. Anticipated Residues for Dietary Risk Assessment. CBTS#'s 14,274, 14,415, and 14,558. MRID#'s 433308-00, 433308-01, 434034-00, and 434034-01.

Document

Class:

Product

Chem:

Residue 860.1200 Directions for use

Chem: 860.1480 Meat/milk/poultry/eggs

860.1500 Crop field trials

860.1520 Processed food/feed

860.1540 Anticipated residues

Biochemicals:

DP Barcode: D206401, D208492

MRIDs: 43330800, 43330801, 43403400, 43403401

PC Codes: 128897 lambda-Cyhalothrin

Commodities: Broccoli; Cabbage; Onion, dry bulb; Lettuce, Head; Hops; Sunflower; Peanut; Soybean; Sorghum, Grain; Corn, Field; Corn, sweet; Tomato; Wheat; Cattle, Meat; Cattle, Fat; Cattle, Liver; Cattle, Kidney; Milk; Poultry, Meat; Poultry, fat; Poultry, Liver; Egg; Corn, pop; Corn; Cotton

Administrative #: 010182-00096; 7F03560; 9F03770

Reviewers: José J. Morales

Review Elizabeth T. Haeberer

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Approver:

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WP Document: Cyhaloth.0

MEMORANDUM:

SUBJECT: PP#'s 9F3770 and 7F3560. Cyhalothrin. Anticipated Residues for Dietary Risk Assessment. CBTS#'s 14,274, 14,415, and 14,558. DP Barcodes D206401 and D208492. MRID#'s 433308-00, 433308-01, 434034-00, and 434034-01.

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and
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At the request of Zeneca Ag Products, Technical Assessment Systems, Inc. (TAS), has conducted a chronic exposure analysis for residues of Karate® insecticide resulting from field crop treatment and from food handling establishment uses. The report, dated 8/8/94, provides data on the percent of the reference dose for all established and pending crop tolerances; and dietary exposure using anticipated residues from field residue trials, established tolerances, processing data, and market share data. A supplemental submission, dated 10/12/94, provided data on the percent of reference dose resulting from dermal application of lambda-cyhalothrin to beef cattle only as well as dermal plus oral exposure.

2

CONCLUSIONS

1. The Updated Livestock Feeds Table for Subdivision O (Residue Chemistry) of the Pesticide Assessment Guidelines (April 1994) no longer lists soybean forage, soybean hay, grain sorghum forage, grain sorghum fodder, and peanut hay as being under grower control. Feeding restrictions are not considered practical, and hence, residue data must be generated before permanent tolerances can be established on any of the RACS associated with soybeans, grain sorghum or peanuts. The residue data should be collected from the same number of field trials with the same geographic distribution as were the residue data on the other RACs of these crops. In the meantime, tolerances with expiration dates can be established on soybeans, peanuts, peanut hulls, sorghum grain, and sorghum grain dust based on the residue data already submitted. Also, the feeding restrictions on forages, hays and fodders of these crops should remain on the label while data are being generated.
2. Anticipated residues for lambda-cyhalothrin are estimated in Table XII for all of the pending tolerances for this chemical. The anticipated residues will be based on the average residue found in field trials only. These average residues can be corrected for percent of crop treated in DRES analysis. Results of processing studies will be used to account for changes in residue levels due to processing (both commercial and other types of processing). Commercial peanut oil, soybean oil, sunflower oil, and corn oil are deodorized, therefore, the DRES run for these commodities should use the anticipated residues for deodorized oils. A summary table of anticipated residues is duplicated below.

Summary Table of Lambda-cyhalothrin Anticipated Residues

Commodity	Average Residue From Crop Field Trials (ppm)	Processing Factor	Anticipated Residue (ppm)
Broccoli	0.20	--	0.20
Cabbage	0.15	--	0.15
Onions (Dry Bulb)	0.03	--	0.03
Lettuce (Head)	0.40	--	0.40
Spent Hops	3.9	--	3.9
Sunflower Seed	0.03	--	0.03
Sunflower Forage	0.05	--	0.05

Commodity	Average Residue From Crop Field Trials (ppm)	Processing Factor	Anticipated Residue (ppm)
Sunflower Hulls		2.3	0.07
Sunflower Presscake		0.18	0.005
Sunflower Crude Oil		0.75	0.02
Sunflower Deodorizer Distillates		1.0	0.03
Sunflower Solvent Extracted Presscake		1.0	0.03
Sunflower Refined Oil		0.71	0.02
Sunflower Soapstock		0.11	0.003
Sunflower Refined Bleached Oil		0.79	0.02
Sunflower Refined Bleached Deodorized Oil		0.57	0.02
Sunflower Solvent Extracted Crude Oil		1.5	0.05
Peanuts	0.02	--	0.02
Peanuts Hulls	0.02	--	0.02
Peanuts, Deodorized Oil		1.0	0.02
Peanut Meal		1.0	0.02
Peanuts, Soapstock		1.0	0.02
Peanuts, Crude Oil		2.0	0.04
Peanuts, Refined Oil		3.0	0.06

Commodity	Average Residue From Crop Field Trials (ppm)	Processing Factor	Anticipated Residue (ppm)
Soybeans	0.01	--	0.01
Soybeans Hulls		0.50	0.005
Soybeans Meal		0.50	0.005
Soybeans, Crude Oil		0.50	0.005
Soybeans, Refined Oil		0.50	0.005
Soybeans, Soapstock		0.50	0.005
Sorghum Grain	0.07	--	0.07
Sorghum, Grain Dust		7.6	0.53
Sorghum, Flour		1.0	0.07
Field Corn Forage	0.02	--	0.02
Field Corn Silage	0.08	--	0.08
Field Corn Fodder	0.22	--	0.22
Field Corn Grain	0.01	--	0.01
Field Corn Flour		2.0	0.02
Field Corn, Grits		1.0	0.01
Field Corn, Oil		1.0	0.01
Field Corn, Starch		1.0	0.01
Sweet Corn	0.01	--	0.01
Sweet Corn Forage	1.8	--	1.8
Tomatoes	0.03	--	0.03
Tomatoes, Wet Pomace		8.8	0.26

Commodity	Average Residue From Crop Field Trials (ppm)	Processing Factor	Anticipated Residue (ppm)
Tomatoes, Dry Pomace		54	1.6
Tomatoes, Puree		0.29	0.009
Tomatoes, Catsup		0.23	0.007
Tomatoes, Paste		0.34	0.01
Tomatoes, Juice		0.09	0.003
Wheat Grain	0.02	--	0.02
Wheat Hay	0.02		0.02
Wheat Straw	0.51	--	0.51
Wheat Forage	0.43	--	0.43
Wheat Bran		3.0	0.06
Wheat Middlings		1.1	0.02
Wheat Shorts, Germ		1.3	0.03
Wheat, Low Grade Flour		0.66	0.01
Wheat, Patent Flour		0.66	0.01
Wheat, Grain Dust		33	0.66
Beef Muscle ¹			0.02
Beef Fat ¹			0.46
Beef Liver ¹			0.008
Beef Kidney ¹			0.03
Beef Muscle ²			0.04
Beef Fat ²			0.86
Beef Liver ²			0.03
Beef Kidney ²			0.06

Commodity	Average Residue From Crop Field Trials (ppm)	Processing Factor	Anticipated Residue (ppm)
Milk			0.10
Poultry Muscle			0.0002
Poultry Fat			0.003
Poultry Liver			0.00007
Eggs			0.0005

- 1 - Anticipated residues do not include contribution from dermal application.
2 - Anticipated residues include contribution from dermal application.

RECOMMENDATION

TOX considerations permitting, CBTS recommends that the proposed tolerances for residues of lambda-cyhalothrin and its epimer in/on soybean seed at 0.01 ppm; peanuts and peanut hulls at 0.05 ppm; and sorghum grain at 0.20 ppm and sorghum grain dust at 1.5 ppm be established with an expiration date. During the time period of the tolerance, the petitioner will need to generate residue data on various animal feed items.

For an interim dietary exposure and risk assessment, we recommend using average residues from data reported in the residue field trials as the best estimate of lambda-cyhalothrin residues in food and feed commodities. Estimates have been provided for processed commodities where data are available. DRES analysis should correct for percent crop treated, if possible, since the average residues were derived from field trial data (as opposed to monitoring data).

We recommend that two DRES analyses should be carried out: the first should not include residues in cattle reflecting dermal application; the second should include the dermal contribution.

Note to the PM:

A complete copy of this review should be sent to the registrant.

DETAILED CONSIDERATIONS

TOLERANCES

Tolerances, to expire August 30, 1991, were established for residues of the insecticide lambdacyhalothrin [$1\alpha(\underline{S}^*)$, $3\alpha(\underline{Z})$]-(\pm)-cyano-(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate] in/on cattle, goats, hogs, horses, and sheep fat at 0.02 ppm; cattle, goats, hogs, horses, and sheep meat and mbyp at 0.01 ppm; cottonseed at 0.05 ppm; and milkfat (reflecting 0.01 ppm in whole milk) at 0.25 ppm (40 CFR §180.438). A tolerance with expiration date of 11/15/94 was established for residues of lambdacyhalothrin and its epimer in/on cottonseed at 0.05 ppm (telephone conversation between J. Morales (CBTS) and S. Moats (RD) on 10/27/94). CBTS has recommended for the establishment of permanent tolerances for residues of lambdacyhalothrin and its epimer in/on broccoli at 0.4 ppm; cabbage at 0.4 ppm; lettuce, head at 2.0 ppm; onions and garlic at 0.1 ppm; sweet corn (k+cwhr) at 0.05 ppm; tomatoes at 0.1 ppm; tomato pomace, wet or dry at 6.0 ppm; soybeans, seed at 0.01 ppm; corn, grain, field, pop and seed at 0.05 ppm; corn grain, flour at 0.15 ppm; corn, forage at 6.0 ppm; corn, fodder at 1.0 ppm; peanuts at 0.05 ppm; peanuts, hulls at 0.05 ppm; wheat grain at 0.05 ppm; wheat forage, straw, and grain dust at 2.0 ppm; wheat, hay at 2.0 ppm; wheat bran at 0.2 ppm; sorghum, grain at 0.2 ppm; sorghum, grain dust at 1.5 ppm; sunflower, seed at 0.05 ppm; sunflower seed hulls at 0.07 ppm; fat of poultry at 0.02 ppm; meat and mbyp of cattle, goats, hogs, horses, and sheep at 0.2 ppm; fat of cattle, goats, hogs, horses, and sheep at 3.0 ppm; meat, mbyp, and eggs of poultry at 0.01 ppm; and milkfat (reflecting 0.2 ppm in whole milk) at 5.0 ppm [M. Flood's memo of 5/16/94].

A food additive tolerance of 10.0 ppm in/on dried hops was recently established under 40 CFR §185.1310 as a result of FAP#0H5599 (57 FR 32440).

USE PATTERNS

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

Broccoli

For control of alfalfa looper, cabbage looper, imported cabbageworm, southern cabbageworm, cutworms, and cabbage webworm apply 0.015 to 0.025 lbs. ai/A. For control of diamondback moth, aphids, armyworm, beet armyworm, fall armyworm, yellowstriped

armyworm, corn earworm, flea beetle, japanese beetle, vegetable weevil, grasshoppers, leafhoppers, stinkbugs, plant bugs, meadow spittlebug, and spider mites apply 0.02 to 0.03 lbs. ai/A. Apply as required by scouting, usually at intervals of 5 or more days. 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. Do not apply within 1 day of harvest. Do not apply more than 0.24 lbs. ai/A/season.

Cabbage

For control of alfalfa looper, cabbage looper, imported cabbageworm, southern cabbageworm, cutworms, and cabbage webworm apply 0.015 to 0.025 lbs. ai/A. For control of diamondback moth, aphids, armyworm, beet armyworm, fall armyworm, yellowstriped armyworm, corn earworm, flea beetle, japanese beetle, vegetable weevil, grasshoppers, leafhoppers, stinkbugs, plant bugs, meadow spittlebug, and spider mites apply 0.02 to 0.03 lbs. ai/A. Apply as required by scouting, usually at intervals of 5 or more days. 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. Do not apply within 1 day of harvest. Do not apply more than 0.24 lbs. ai/A/season.

Corn, Field, Seed, Pop

Karate® may be applied by ground or air at the rate of 0.015 to 0.03 lbs. ai/A as required by scouting, or locally prescribed corn growth stages, usually at intervals of 7 or more days. Do not apply within 21 days of harvest. When applying by air, apply in a minimum of 2 gallons of water per acre. Do not apply more than 0.06 lb ai/A (0.48 pints) after silk initiation. Do not apply more than 0.03 lb ai/A (0.24 pints) after corn has reached the milk stage (yellow kernels with milky fluid). Do not apply more than 0.12 lb ai/A/season.

Cotton

Karate® may be applied by ground or air at the rate of 0.01 to 0.04 lbs. ai/A as required by scouting, usually at intervals of 5 to 7 days. Applications may also be made with equipment adapted and calibrated for ULV sprays. Karate® may be mixed with once-refined vegetable oil and applied in a minimum of at least one quart of finished spray per acre. Do not apply within 21 days of harvest. Do not graze livestock in treated areas. Do not apply more than 1.6 pints (0.2 lbs. ai/A) per acre per season. Do not make more than a total of 10 synthetic pyrethroid applications (of one product or combination of products) to a cotton crop in one growing season.

Lettuce (Head)

Karate® may be applied by ground or air at the rate of 0.015 to 0.03 lbs. ai/A as required by scouting, usually at intervals of 5 or more days. When applying by air, apply in a

minimum of 2 gallons of water per acre. Do not apply within 1 day of harvest. Do not apply more than 0.3 lbs. ai/A/season.

Onions (Bulb) and Garlic

For control of cutworms, seedcorn maggot adults, onion maggot adults and leafminer adults apply 0.015 to 0.025 lbs. ai/A. For control of armyworms, onion thrips, western flower thrips, aphids, plant bugs and stink bugs apply 0.02 to 0.03 lbs. ai/A. Apply as required by scouting, usually at intervals of 5 or more days. Apply with ground or air equipment using sufficient water and application methods to obtain full coverage of foliage. When applying by air, apply in a minimum of 2 gallons water per acre. Do not apply within 14 days of harvest. Do not apply more than 0.24 lbs. ai/A/season.

Peanuts

Karate® may be applied by ground or air at levels of 0.015-0.03 lb ai/A at intervals required by scouting, usually 7 or more days. When applying by air, apply in a minimum of 2 gallons of water per acre. Do not apply within 14 days of harvest. Do not apply more than 0.12 lb ai/A/season. Do not graze livestock in treated areas. Do not use treated vines or hay for animal feed.

We note that there is a restriction against the feeding of peanut hay to animals. According to the Updated Livestock Feeds Table for Subdivision O (Residue Chemistry) of the Pesticide Assessment Guidelines (E. Saito and E. Zager memo of 6/2/94), peanut hay is not under grower control and is now considered a rac and an animal feed item. Therefore, the label restriction against feeding hay to livestock is no longer practical. The petitioner needs to submit residue data on this commodity. Data should be obtained on hay from the same number of trials as were previously carried out for peanuts. Time limited tolerances may be issued for the following peanut racs until the submission of residue data for peanut hay: Peanuts at 0.05 ppm; peanuts, hulls at 0.05 ppm.

Sorghum (Grain)

Karate® may be applied by ground or air at levels of 0.015 to 0.03 lbs. ai/A as required by scouting, usually at intervals of 5 or more days. When applying by air, apply in a minimum of 2 gallons of water per acre. Do not apply within 30 days of harvest. Do not apply more than 0.08 lbs. ai/A/season. Do not apply more than 0.06 lbs. ai/A/season after crop emergence. Do not apply more than 0.02 lbs. ai/A/season once crop is in soft dough stage. Do not graze livestock in treated areas or harvest for fodder, silage or hay.

We note that there is a restriction against the feeding of sorghum fodder to animals. According to the Updated Livestock Feeds Table for Subdivision O (Residue Chemistry) of the Pesticide Assessment Guidelines (E. Saito and E. Zager memo of 6/2/94), sorghum forage,

silage, or fodder are not under grower control and are now considered racs and animal feed items. Therefore, the label restriction against feeding fodder to livestock is no longer practical. The petitioner needs to submit residue data on these commodities. Silage samples should include the whole aerial portion and be harvested at late dough/early dent stage. Silage may be analyzed immediately after collection, or after ensiling for 3 weeks maximum and reaching a pH of 4.2 or less. Residue data on forage would cover silage. Hay is no longer considered to be a rac. Time limited tolerances may be issued for the following sorghum racs until the submission of residue data for sorghum fodder, forage and silage: sorghum grain at 0.2 ppm; and sorghum aspirated grain fractions at 1.5 ppm.

Soybeans

For control of corn earworm, velvetbean caterpillar, green cloverworm, cabbage looper, saltmarsh caterpillar, woollybear caterpillar, cutworms, bean leaf beetle, mexican bean beetle, cucumber beetles, three-cornered alfalfa hopper, potato leafhopper and thrips apply 0.015 to 0.025 lbs. ai/A. For control of fall armyworm, yellowstriped armyworm, tobacco budworm, webworms, european corn borer, japanese beetle (adult), blister beetles, stink bugs, plant bugs, and grasshoppers apply 0.025 to 0.03 lbs. ai/A. For control of beet armyworm, soybean looper, lesser cornstalk borer, and spider mites apply 0.03 lbs. ai/A. Apply by scouting, usually at intervals of 5 or more days. 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. Do not apply within 45 days of harvest. Do not apply more than 0.06 lbs. ai/A/season.

We note that there is a restriction against the feeding of soybean forage and hay to animals. According to the Updated Livestock Feeds Table for Subdivision O (Residue Chemistry) of the Pesticide Assessment Guidelines (E. Saito and E. Zager memo of 6/2/94), soybean hay and forage are not under grower control and are now considered racs and animal feed items. Therefore, the label restriction against feeding forage and hay to livestock is no longer practical. The petitioner needs to submit residue data on these commodities. The number of field trials as well as the geographic representation should match that used to generate the data for seed. Time limited tolerances may be issued for the following soybean rac until the submission of residue data for soybean forage and hay: soybean, seed at 0.01 ppm.

Sunflowers

Karate® may be applied by ground or air equipment at the rate of 0.01 to 0.03 lbs. ai/A as required by scouting, usually at intervals of 5 or more days. When applying by air, apply in a minimum of 2 gallons of water per acre. Do not apply within 45 days of harvest. Do not apply more than 0.12 lbs. ai per acre per season. Do not apply more than 0.09 lbs. ai/A/season after bloom initiation. Foraging is to be restricted to up to six weeks after a single application.

Sweet Corn

Karate® may be applied by ground or air at the rate of 0.02 to 0.03 lbs. ai/A as required by scouting, or locally prescribed corn growth stages, usually at intervals of 4 or more days. When applying by air, apply in a minimum of 2 gallons of water per acre. Do not apply within 1 day of harvest. Do not apply more than 0.48 lbs. ai/A/season.

Tomatoes and Tomatillos

Karate® may be applied by ground or air at the rate of 0.015 to 0.03 lbs. ai/A as required by scouting, usually at intervals of 5 or more days. When applying by air, apply in a minimum of 2 gallons of water per acre. Do not apply within 5 days of harvest. Do not apply more than 0.36 lbs. ai/A/season. Do not use on varieties in which the mature tomatoes will be less than one inch in diameter (such as cherry tomatoes).

Wheat, Wheat Hay, and Triticale

Karate® may be applied by ground or air at the rate of 0.015 to 0.03 lbs. ai/A as required by scouting, usually at intervals of 5 or more days. When applying by air, apply in a minimum of 2 gallons of water per acre. Do not apply within 30 days of harvest. Do not apply more than 0.06 lbs. ai/A/season.

NATURE OF THE RESIDUE

The nature of the residue in plants is adequately understood (PP#7F3560/7H5543, M. Flood, memo of 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. A cabbage metabolism study indicated that in that race the cis- and trans- cyclopropanecarboxylic acids were the major constituents.

CB-1 and TB-1 have 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 (See memo from P. Hurley to M. Flood, 1/3/92.). The residue to be regulated is lambda-cyhalothrin and its epimer.

The nature of the residue in animals is adequately understood. 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-methylcyclopropanecarboxylic acid (OH-CPA) and 4-hydroxy-3-phenoxybenzoic acid (4'-OH-3PBACid) may be present in significant quantities. Although OH-CPA has not been definitively identified as a rat metabolite, a residue transfer study in which cows were fed dietary levels of 8, 25 or 80 ppm lambda-cyhalothrin demonstrated that at the maximum level of lambda-cyhalothrin in the diet (≤ 8 ppm) OH-CPA levels in tissue would not exceed 0.01 ppm (M. Flood, memo of 8/31/92). As in the case with plants, the residue to be regulated is lambda-cyhalothrin and its epimer.

ANALYTICAL METHODOLOGY

Plants

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

Animals

The analytical method for determination of residues of lambda-cyhalothrin in meat, milk, poultry and eggs is ICI Method 86, reviewed in M. Firestone's memo of 1/22/86 (PP#6F3318). Lambda-cyhalothrin and its epimer are extracted from milk or animal tissue with 50 percent acetone:hexane. After removal of the aqueous layer, the organic fraction is cleaned up with a Florisil column prior to determination by GC using a ^{63}Ni electron capture detector. The limit of determination is 0.01 ppm. This method has undergone successful EPA Method Validation (PP#6F3318/7F3488, E. Greer, memo of 9/30/87; S. Brooks, memo of 10/30/87).

Multiresidue Testing

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

RESIDUE DATA

The summary of residue data, processing studies, and dietary burden calculations appear in the following report:

"CHRONIC DIETARY EXPOSURE AND RISK ASSESSMENT: RESIDUES OF KARATE® INSECTICIDE"; J. L. Kidwell, B. M. Polakoff; B. J. Petersen, J. R. Tomerlin; 8/8/94; Project Id: Karate 94-01 (MRID# 433308-01).

Field trials were available for broccoli, cabbage, field corn, sweet corn, onions, tomatoes, lettuce, peanuts, sorghum, soybeans, sunflowers, and wheat. Average residues were calculated for the parent compound and the epimer. The petitioner stated that both the parent and the epimer were assumed to be present at half the limit of detection for those crops for which all samples analyzed were below the sensitivity of the analytical method. For crops in which some samples had detectable residues and other samples were nondetectable, the full limit of detection was assumed for nondetects. However, CBTS policy is that for every residue that is below the limit of detection both the parent compound and the epimer were assumed to be present at half the limit of detection. This is why our numbers differ from those submitted by the petitioner. These average residues are shown in Table I.

Table I. Lambda-cyhalothrin Field Trial Average Results

RAC	Average Residue From Crop Field Trials ¹ (ppm)
Broccoli	0.20
Cabbage	0.15
Field Corn Forage	0.02
Field Corn Silage	0.08
Field Corn Fodder	0.22
Field Corn Grain	0.01
Sunflower Seed	0.03
Sunflower Forage	0.05

RAC	Average Residue From Crop Field Trials ¹ (ppm)
Sweet Corn	0.01
Sweet Corn Forage	1.8
Hops	3.9
Lettuce (Head)	0.40
Onions (Dry Bulb)	0.03
Peanuts	0.02
Peanut Hulls	0.02
Sorghum Grain	0.07
Soybeans	0.01
Tomatoes	0.03
Wheat Grain	0.02
Wheat Hay	0.02
Wheat Straw	0.51
Wheat Forage	0.43

1 - Average residue includes the parent compound and its epimer.

Processing studies were available for sweet corn, field corn, peanuts, sorghum, soybeans, tomatoes, and wheat. The submitted data by the petitioner does not include sunflower processing studies, but these data will be added by CBTS. Processing factors are presented for those fractions in which residues increased or decreased during processing. Processing factors for commodities that contained the same residue levels as the rac were assumed to be 1. Also, for every residue that is below the limit of detection both the parent compound and the epimer were assumed to be present at half the limit of detection. These studies are shown in Table II. There were no FDA monitoring data available for lambda-cyhalothrin.

15

Table II. Summary of Lambda-cyhalothrin Processing Study Results

RAC	Processed Commodity	Residues in RAC (ppm) ¹	Residues in Processed Commodity (ppm) ¹	Processing Factor
Field Corn ²				
	Flour	0.02	0.04	2
Peanuts ³				
	Crude Oil	0.01	0.02	2.0
	Refined Oil	0.01	0.03	3
Sorghum ⁴				
	Dust	0.06	0.46	7.6
Soybeans				
	Hulls	0.02	0.01	0.50
	Meal	0.02	0.01	0.50
	Crude Oil	0.02	0.01	0.50
	Refined Oil	0.02	0.01	0.50
	Soapstock	0.02	0.01	0.50
Tomatoes				
	Wet Pomace	0.35	3.1	8.8

RAC	Processed Commodity	Residues in RAC (ppm) ¹	Residues in Processed Commodity (ppm) ¹	Processing Factor
	Dry Pomace	0.35	19	54
	Puree	0.35	0.10	0.29
	Catsup	0.35	0.08	0.23
	Paste	0.35	0.12	0.34
	Juice	0.35	0.03	0.09
Wheat				
	Bran	0.03	0.09	3.0
	Middlings	0.03	0.03	1.1
	Shorts, Germ	0.03	0.04	1.3
	Low Grade Flour	0.03	0.02	0.66
	Patent Flour	0.03	0.02	0.66
	Dust	0.03	0.98	33
Sunflowers ⁵				
	Hulls	0.28	0.63	2.3
	Presscake	0.28	0.05	0.18
	Crude Oil	0.28	0.21	0.75
	Refined Oil	0.28	0.20	0.71
	Soapstock	0.28	0.03	0.11
	Refined Bleached Oil	0.28	0.22	0.79
	Refined Bleached Deodorized Oil	0.28	0.16	0.57

RAC	Processed Commodity	Residues in RAC (ppm) ¹	Residues in Processed Commodity (ppm) ¹	Processing Factor
	Solvent Extracted Crude Oil	0.28	0.41	1.5

1 - Residue includes the parent compound and its epimer.

2 - Processing factor for all other processed fractions (grits, oil, starch) = 1.

3 - Processing factor for all other processed fractions (refined, bleached, deodorized oil; meal; and soapstock) = 1.

4 - Processing factor for flour = 1.

5 - Processing factor for deodorizer distillates and solvent extracted presscake = 1.

MEAT, MILK, POULTRY AND EGGS

Residues of lambda-cyhalothrin in poultry, milk, and eggs could result from secondary residues in livestock feed commodities and in meat from a combination of secondary residues in livestock feed commodities and direct dermal uses. Therefore, residues in meat, fat, and mbyp would be the sum of secondary residues and residues resulting from dermal uses.

Dermal Uses

SABER® Pour-On Insecticide is to be used on beef cattle for control of lice and horn flies. The product is applied down the backline at the rate of 10 mL (1/3 fl. oz) per head for cattle weighing less than 600 lb or at the rate of 15 mL (1/2 fl. oz) per head for cattle weighing more than 600 lbs. The maximum number of applications is 4 within any six month period. Do not apply to lactating or dry dairy cows.

A dermal study was submitted in PP#9F3770 and discussed in M. Flood's memo of 1/25/90. Briefly, twenty nine cattle of mixed breed and sex weighing between 300 kg and 340 kg were used in this study. The animals were assigned to five groups of five animals (groups A to E) for treatment at the recommended therapeutic dose rate, a group of two animals (group F) for treatment with an overdose of the formulation and a group of two animals (group G, not shown) which were untreated and acted as control animals. All animals in groups A to F were treated with 1% w/v lambda-cyhalothrin (SABER® Pour-On Insecticide) at intervals of 2 weeks for a total of four treatments. Group A animals were killed on Day 42 within 6 hours of the final treatment. Group F animals were also killed within 6 hours of final treatment but after the group A animals. Group B, C, D, and E animals were killed at 3, 7, 14, and 28 days respectively after final treatment. At slaughter the entire liver, both kidneys complete with perirenal fat, and samples of subcutaneous fat and quadriceps muscle were excised from each animal, sealed into plastic bags and immediately frozen prior to shipment in dry ice. Results of

residue analyses are given in Table III. No discussion about dermal studies were provided by the petitioner in MRID#433308-01 and MRID#434034-01.

Table III. Tissue Residues of Lambda-cyhalothrin Resulting From Dermal Use

Animal Group	Tissue Residues of Lambda-cyhalothrin (ppm)				
	Sub. Cut. Fat	Perirenal Fat	Muscle	Kidney	Liver
A	0.080-0.304	0.182-0.483	<0.003-0.011	<0.003-0.040	<0.005-0.017
B	0.080-0.229	0.158-0.510	0.005-0.008	0.006-0.017	0.006-0.028
C	0.107-0.438	0.288-0.769	<0.003-0.038	0.025-0.055	<0.005-0.027
D	0.016-0.299	0.049-0.568	<0.003-0.005	<0.003-0.008	<0.005-0.008
E	0.039-0.118	0.031-0.217	--	--	--
F	0.121-0.293	0.522-0.569	<0.003-0.031	0.012-0.030	0.006-0.016

In the calculation of anticipated residues, the average value for fat, muscle, kidney and liver will be used. These average values were taken from a total of 29 cows. Averages were taken for each group of cows and then each average were used to calculate a final average for fat, muscle, kidney, and liver. Average values for fat include values for subcutaneous and perirenal fat. These average values were 0.399 ppm for fat, 0.019 ppm for muscle, 0.030 ppm for kidney, and 0.019 ppm for liver. These values will be added to those resulting from oral ingestion for beef cattle to obtain the anticipated residue.

Secondary Residues

A feeding study in which lambda-cyhalothrin was fed to three groups of three cows at levels of 1.0 ppm, 5.0 ppm, and 25 ppm for 28-30 days was submitted for PP#6F3318 and reviewed by M. Firestone in him memo of 1/22/86. Average levels of parent lambda-cyhalothrin in milk from cows fed at the three feeding levels were 0.03 ppm, 0.08 ppm, and 0.85 ppm. Average levels in tissue at the three feeding levels were: muscle -- 0.0066 ppm, 0.0366 ppm, and 0.1733 ppm; fat -- 0.1775 ppm, 0.9463 ppm; and 4.008 ppm; liver -- 0.0116 ppm, 0.0083 ppm, and 0.0683 ppm; and kidney -- 0.0116 ppm, 0.0416 ppm, and 0.231 ppm.

A poultry feeding study was reviewed by S. Willett (S. Brooks) in PP#7F3488 (memo of 8/13/87). Seven groups of 10 laying hens were fed containing 1.0 ppm, 5.0 ppm, and 25 ppm lambda-cyhalothrin for up to 28 consecutive days. Residues did not accumulate and declined when feeding of the treated diet ceased. Average residues in tissues and eggs are given in Table IV. The residue levels for eggs are the mean plateau residues.

Table IV. Average Residue Levels (ppm) of Lambda-cyhalothrin in Egg and Tissue of Hens Fed at Three Levels

Tissue	Feeding Levels (ppm)		
	1.0	5.0	25.0
Eggs	0.003	0.010	0.050
Liver	0.003	0.003	0.005
Muscle	0.002	0.003	0.020
Fat	0.022	0.062	0.340

Average dietary burdens were calculated for beef and dairy cattle, poultry, and swine using average residues from field trials at the proposed use pattern. Calculations of dietary burdens were not made using tolerance levels. Although the feed items used in this review are the same ones that the petitioner has chosen, and the petitioner stated that residues in milk, meat, eggs, and poultry were calculated by assuming mean residues (adjusted for dry matter percentage) in animal feed items at proportions specified in the Subdivision O Guidelines, our results differ from those listed in Table 4 of MRID#433308-00. CBTS recalculated the dietary burdens based on the feed commodities provided by the petitioner. The average dietary burden was calculated using the following formula: Dietary burden (ppm) = % Diet/% DM x average residue (ppm). It should be noted that these are not actual diets. They represent the worst case scenario of lambda-cyhalothrin exposure in animals.

Calculation of the average dietary burden for lambda-cyhalothrin in beef cattle is shown in Table V.

Table V. Calculation of Average Dietary Burden for Lambda-cyhalothrin in Beef Cattle

Feed Item	%DM	% of Diet	Average Residue (ppm)	Dietary Burden (ppm)
Spent Hops	86	20	3.9	0.907
Sweet Corn Forage	48	40	1.81	1.51
Tomato Pomace, Dry	92	25	1.68	0.456
Total		85		2.873

Calculation of the average dietary burden for lambda-cyhalothrin in dairy cattle is shown in Table VI.

Table VI. Calculation of Average Dietary Burden for Lambda-cyhalothrin in Dairy Cattle

Feed Item	%DM	% of Diet	Average Residue (ppm)	Dietary Burden (ppm)
Spent Hops	86	10	3.9	0.453
Sweet Corn Forage	48	50	1.81	1.88
Tomato Pomace, Dry	92	10	1.68	0.182
Tomato Pomace, Wet	15	20	0.264	0.352
Total		90		2.867

Calculation of the average dietary burden for lambda-cyhalothrin in poultry is shown in Table VII.

Table VII. Calculation of Average Dietary Burden for Lambda-cyhalothrin in Poultry

Feed Item	%DM	% of Diet	Average Residue (ppm)	Dietary Burden (ppm)
Sorghum Grain	86	80	0.07	0.065
Tomato Pomace, Dry	92	10	1.68	0.182
Total		90		0.247

Calculation of the average dietary burden for lambda-cyhalothrin in swine (based on the cattle feeding study) is shown in Table VIII.

Table VIII. Calculation of Average Dietary Burden for Lambda-cyhalothrin in Swine

Feed Item	%DM	% of Diet	Average Residue (ppm)	Dietary Burden (ppm)
Sweet Corn Forage	48	15	1.81	0.565
Wheat, Aspirated Grain Fractions	88	20	0.784	0.178
Sorghum, Aspirated Grain Fractions	85	20	0.495	0.116
Wheat Forage	25	15	0.430	0.258
Tomato Pomace, Dry	92	10	1.68	0.182
Total		80		1.299

Estimates of residues in livestock commodities fed average residues (from field trials) of lambda-cyhalothrin in their feed are calculated in Tables IX to XI. The anticipated residues were calculated using linear regression. The linear regression equation is $y = ax + b$, where a is the slope of the dose response curve and b is the y intercept, which is equal to zero. There are no monitoring data available from USDA-FSIS for lambda-cyhalothrin.

Table IX. Estimates of Secondary Lambda-cyhalothrin Residues (ppm) in Beef and Dairy Cattle

Livestock Tissue	Dietary Burden (ppm)	Estimated Residue (ppm)
Milk	2.867	0.097
Muscle	2.873	0.020
Fat	2.873	0.460
Liver	2.873	0.008
Kidney	2.873	0.030

Table X. Estimates of Secondary Lambda-cyhalothrin Residues (ppm)
in Poultry

Livestock Tissue	Dietary Burden (ppm)	Estimated Residue (ppm)
Eggs	0.247	0.0005
Muscle	0.247	0.0002
Fat	0.247	0.003
Liver	0.247	0.00007

Table XI. Estimates of Secondary Lambda-cyhalothrin Residues (ppm)
in Swine

Livestock Tissue	Dietary Burden (ppm)	Estimated Residue (ppm)
Muscle	1.299	0.009
Fat	1.299	0.210
Liver	1.299	0.004

ANTICIPATED RESIDUES

The anticipated residues for lambda-cyhalothrin will be based on the average residue found in field trials only. These average residues can be corrected for percent of crop treated in DRES analysis. Results of processing studies will be used to account for changes in residue levels due to processing (both commercial and other types of processing). Commercial peanut

oil, soybean oil, sunflower oil, and corn oil are deodorized, therefore, the DRES run for these commodities should use the anticipated residues for deodorized oils. Estimates of residues in meat, milk, poultry, and eggs are discussed in the section above.

Residue estimates to be used in DRES are found in Table XII.

Table XII. Determination of Anticipated Residues for Lambda-cyhalothrin

Commodity	Average Residue From Crop Field Trials (ppm)	Processing Factor	Anticipated Residue (ppm)
Broccoli	0.20	--	0.20
Cabbage	0.15	--	0.15
Onions (Dry Bulb)	0.03	--	0.03
Lettuce (Head)	0.40	--	0.40
Spent Hops	3.9	--	3.9
Sunflower Seed	0.03	--	0.03
Sunflower Forage	0.05	--	0.05
Sunflower Hulls		2.3	0.07
Sunflower Presscake		0.18	0.005
Sunflower Crude Oil		0.75	0.02
Sunflower Deodorizer Distillates		1.0	0.03
Sunflower Solvent Extracted Presscake		1.0	0.03
Sunflower Refined Oil		0.71	0.02
Sunflower Soapstock		0.11	0.003

Commodity	Average Residue From Crop Field Trials (ppm)	Processing Factor	Anticipated Residue (ppm)
Sunflower Refined Bleached Oil		0.79	0.02
Sunflower Refined Bleached Deodorized Oil		0.57	0.02
Sunflower Solvent Extracted Crude Oil		1.5	0.05
Peanuts	0.02	--	0.02
Peanuts Hulls	0.02	--	0.02
Peanuts, Deodorized Oil		1.0	0.02
Peanut Meal		1.0	0.02
Peanuts, Soapstock		1.0	0.02
Peanuts, Crude Oil		2.0	0.04
Peanuts, Refined Oil		3.0	0.06
Soybeans	0.01	--	0.01
Soybeans Hulls		0.50	0.005
Soybeans Meal		0.50	0.005
Soybeans, Crude Oil		0.50	0.005
Soybeans, Refined Oil		0.50	0.005
Soybeans, Soapstock		0.50	0.005
Sorghum Grain	0.07	--	0.07
Sorghum, Grain Dust		7.6	0.53
Sorghum, Flour		1.0	0.07

Commodity	Average Residue From Crop Field Trials (ppm)	Processing Factor	Anticipated Residue (ppm)
Field Corn Forage	0.02	--	0.02
Field Corn Silage	0.08	--	0.08
Field Corn Fodder	0.22	--	0.22
Field Corn Grain	0.01	--	0.01
Field Corn Flour		2.0	0.02
Field Corn, Grits		1.0	0.01
Field Corn, Oil		1.0	0.01
Field Corn, Starch		1.0	0.01
Sweet Corn	0.01	--	0.01
Sweet Corn Forage	1.8	--	1.8
Tomatoes	0.03	--	0.03
Tomatoes, Wet Pomace		8.8	0.26
Tomatoes, Dry Pomace		54	1.6
Tomatoes, Puree		0.29	0.009
Tomatoes, Catsup		0.23	0.007
Tomatoes, Paste		0.34	0.01
Tomatoes, Juice		0.09	0.003
Wheat Grain	0.02	--	0.02
Wheat Hay	0.02		0.02
Wheat Straw	0.51	--	0.51
Wheat Forage	0.43	--	0.43
Wheat Bran		3.0	0.06
Wheat Middlings		1.1	0.02

Commodity	Average Residue From Crop Field Trials (ppm)	Processing Factor	Anticipated Residue (ppm)
Wheat Shorts, Germ		1.3	0.03
Wheat, Low Grade Flour		0.66	0.01
Wheat, Patent Flour		0.66	0.01
Wheat, Grain Dust		33	0.66
Beef Muscle ¹			0.02
Beef Fat ¹			0.46
Beef Liver ¹			0.008
Beef Kidney ¹			0.03
Beef Muscle ²			0.04
Beef Fat ²			0.86
Beef Liver ²			0.03
Beef Kidney ²			0.06
Milk			0.10
Poultry Muscle			0.0002
Poultry Fat			0.003
Poultry Liver			0.00007
Eggs			0.0005

1 - Anticipated residues do not include contribution from dermal application.

2 - Anticipated residues include contribution from dermal application.

cc: RF, Circu., SF, José J. Morales, E. Haeberer, E. Doyle (DRES), PP#'s 9F3770 and 7F3560

7509C: Reviewer (JJM): CM#2: Rm 804-B: 305-7887: typist (JJM): 12/8/94

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