

12-13-94

Residue Chemistry Review

Comments:

Subject:

PP#'s 7F3560/7H5543 (Lambda-cyhalothrin in/on Wheat, Sweet Corn, Sunflowers); 7F3488 (Lambda-cyhalothrin in/on Soybeans); 1F3952/1H5607 (Lambda-cyhalothrin in/on Broccoli, Cabbage, Tomatoes); 1F3992 (Lambda-cyhalothrin in/on Grain Sorghum); 2F4100 (Lambda-cyhalothrin in/on Dry Bulb Onions, Garlic); 2F4114 (Lambda-cyhalothrin in/on Peanuts); 1F3985 (Lambda-cyhalothrin in/on Head Lettuce). Amendment in Response to Review of 5/16/94. Label Amendment request for Karate® on Sunflowers.
MRID#'s: 432963-00, 432963-01, 432963-02, 432947-00, 432947-01.
CBTS#'s: 14036, 14037, 14038, 14039, 14040, 14041, 14042, 14043, 14044, 14045, 14046.

Document

Class:

Product

Chem:

Residue

Chem:

860.1200 Directions for use
860.1380 Storage stability data
860.1500 Crop field trials
860.1520 Processed food/feed
860.1550 Proposed tolerances

Biochemicals:

DP Barcode: D205258, D205260, D205263, D205268, D205272, D205277, D205280, D205281, D205284, D205286, D205287

MRIDs: 43296300, 43296301, 43296302, 43294700, 43294701

PC Codes: 128897 lambda-Cyhalothrin

Commodities: Wheat; Corn, sweet; Sunflower; Soybean; Broccoli; Cabbage; Tomato; Sorghum, Grain; Onion, dry bulb; Garlic; Peanut; Lettuce, Head

Administrative #: 1F03952; 1F03985; 1F03992; 1H05607; 2F04100; 2F04114; 7F03488; 7F03560; 7H05543

Reviewers: José J. Morales

Review R. A. Loranger

Approved on: December 13, 1994

Approver:

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WP Document: Cyhaloth.0

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MEMORANDUM:

SUBJECT: PP#'s **7F3560/7H5543** (Lambda-cyhalothrin in/on Wheat, Sweet Corn, Sunflowers); **7F3488** (Lambda-cyhalothrin in/on Soybeans); **1F3952/1H5607** (Lambda-cyhalothrin in/on Broccoli, Cabbage, Tomatoes); **1F3992** (Lambda-cyhalothrin in/on Grain Sorghum); **2F4100** (Lambda-cyhalothrin in/on Dry Bulb Onions, Garlic); **2F4114** (Lambda-cyhalothrin in/on Peanuts); **1F3985** (Lambda-cyhalothrin in/on Head Lettuce). Amendment in Response to Review of 5/16/94. Label Amendment request for Karate® on Sunflowers.

CBTS#'s: 14036, 14037, 14038, 14039, 14040, 14041, 14042, 14043, 14044, 14045, 14046.

DP Barcodes: D205258, D205260, D205263, D205268, D205272, D205277, D205280, D205281, D205284, D205286, D205287.

MRID#'s: 432963-00, 432963-01, 432963-02, 432947-00, 432947-01.

FROM: José J. Morales, Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

THROUGH: Richard Loranger, Acting Chief
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

TO: Adam Heyward/George LaRocca, PM 13
Insecticide-Rodenticide Branch
Registration Division (7505C)
and
Albin Kocialski, Section Head
Registration Section
Chemical Coordination Branch
Health Effects Division (7509C)

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BACKGROUND

These submissions from Zeneca Ag Products, dated 6/29/94, are responsive to M. Flood's review of 5/16/94. The submissions consist of a revised Section F, a revised Section B, and a response to the soapstock storage stability issue. Also, with this submission, Zeneca Ag Products has submitted a proposal for amended use of Karate® on sunflowers to increase the seasonal use rate from 3 applications/season to 4 applications/season. Zeneca Ag Products is proposing the following tolerances for lambda-cyhalothrin and its epimer in/on sunflowers as a result of this amended use: sunflowers, seed at 0.20 ppm; sunflower, forage at 0.01 ppm; sunflower, hulls at 0.50 ppm; and sunflower, oil at 0.30 ppm.

SUMMARY OF DEFICIENCIES THAT NEED TO BE RESOLVED

A revised Section B and F for sunflowers should be submitted.

CONCLUSIONS AND RECOMMENDATIONS

1. Lambda-cyhalothrin and its epimer have been shown to be stable on soapstock samples under frozen storage conditions for periods up to 34 months.
2. A complete Section F and a revised Section B, as requested in M. Flood's memo of 5/16/94, has been submitted. Therefore, TOX considerations permitting, CBTS recommends that the proposed tolerances of lambda-cyhalothrin and its epimer in/on broccoli at 0.4 ppm; cabbage at 0.4 ppm; corn, grain, field, and pop at 0.05 ppm; corn, fodder at 1.0 ppm; corn, forage at 6.0 ppm; corn, sweet (k+cwhr) at 0.05 ppm; garlic t 0.10 ppm; lettuce, head at 2.0 ppm; onions, dry bulb at 0.10 ppm; tomatoes at 0.10 ppm; wheat, grain at 0.05 ppm; wheat, forage, hay, straw, and grain dust at 2.0 ppm; milk, fat (reflecting 0.20 ppm in whole milk) at 5.0 ppm; meat and mbyp of cattle, goats, hogs, horses, and sheep at 0.20 ppm; fat of cattle, goats, hogs, horses, and sheep at 3.0; meat, fat, mbyp, and eggs of poultry at 0.01 ppm; corn, grain flour at 0.15 ppm; tomato pomace, wet or dry at 6.0 ppm; and wheat, bran at 0.20 ppm be established.

TOX considerations permitting, CBTS recommends that the proposed tolerances for residues of lambda-cyhalothrin and its epimer in/on soybeans at 0.01 ppm; peanuts at 0.05 ppm; peanuts, hulls at 0.05 ppm; 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.

- 3a. The residue data showed maximum residues of lambda-cyhalothrin in/on sunflower seed of 0.15 ppm for ICIA0321, 0.01 ppm for R157836, 0.01 ppm for PP890 and <0.01 ppm for PBACid. Forage samples taken six weeks after planting with intervals between the first application and sampling ranging from 26 to 50 days showed no detectable residues (<0.01 ppm). CBTS concludes that since, from cultural practice considerations, there is no apparent reason for residues in sunflower forage to be lower than in the seed, and that there is no assurance that forage treated more than one time with lambda-cyhalothrin will not be fed to animals, the tolerance level for sunflower forage will have to be set equal to sunflower seed. A revised Section F proposing a tolerance of 0.20 ppm for residues of lambda-cyhalothrin and its epimer in/on sunflower forage is needed.
- 3b. TOX considerations permitting and provided that a revised Section B and F for sunflowers are submitted, CBTS recommends that the proposed tolerance for residues of lambda-cyhalothrin and its epimer in/on sunflower, seeds and sunflower, forage at 0.20 ppm; sunflower, hulls at 0.50 ppm; and sunflower, oil at 0.30 ppm be established.

DETAILED CONSIDERATIONS

The deficiencies listed in CBTS memo of 5/16/94 are outlined below followed by the petitioner's responses and CBTS comments.

CBTS Deficiency #1b

Lambda-cyhalothrin and its epimer have been shown to be stable in processed commodities under frozen storage for periods up to 34 months. The petitioner should explain the discrepancy between the 18-month levels for soapstock reported in the interim and the final reports. Chromatograms from the storage stability study on soapstock should be submitted. (This information should preferably be submitted as a part of PP#7F3488. Because the updated Table II of our Residue chemistry guidelines no longer lists "soapstock" as a significant feed item, storage stability in soapstock is not an issue. However, since these data have already been generated, they remain useful in determining the overall stability profile of the pesticide.)

Petitioner's Response to Deficiency #1b

The discrepancy between the 18 month levels for soapstock in the interim and the final reports was due to an error in the earlier interim report. Discovery of the error did not occur until September 1993 when reviewing the 34 month stability data. The data

presented in the interim report for soapstock had been calculated for the 18 and 34 month data assuming that 10 g of soapstock was originally fortified with lambda-cyhalothrin and R157836 (epimer). This was in error. At the initiation of the study, 10 g aliquots of the commodities were weighed out with the exception of soapstock where only 5 g aliquots weighed out due to insufficient quantities of soapstock available. The results in the interim report were incorrectly calculated on the basis of 10 g aliquot. The results indicated that lambda-cyhalothrin and R157836 (epimer) had declined to about half the level they should have been. The concurrent fortification samples (procedural recoveries run at each time interval) at the 18 and 34 month interval were also made assuming 10 g. These samples were fortified with 1.0 μg of cyhalothrin (ICIA0321 and R157836) which based on a 10g is a fortification level of 0.1 $\mu\text{g/g}$. As only 5 g of soapstock was actually fortified, the level was 0.2 $\mu\text{g/g}$. The concurrent fortification level was shown to be 0.1 $\mu\text{g/g}$ on the chromatograms, as the error was not discovered until after labeling the chromatograms. When calculated on the correct basis of 5 g of soapstock no significant degradation of ICIA0321 and R157836 was shown to occur over the 34 month storage time. This data was presented in the final report.

CBTS Comments

The submitted chromatograms show that there is no significant decline of lambda-cyhalothrin and its epimer in soapstock samples. Worksheet copies were submitted where the above corrections were made.

Deficiency #1b is resolved.

CBTS Deficiency #2a

Proposed tolerances for field corn grain, forage, fodder and corn flour (11/19/92 memo); poultry fat, milkfat (9/1/92 memo); tomato pomace (4/9/92 memo); head lettuce (10/22/91 memo) -- as requested in the cited CBTS memos -- have been submitted. All tolerance values are now appropriate, with one exception. The corn forage tolerance should be proposed at 6.0 ppm, and the sweet corn forage tolerance in PP#7F3560 should be deleted. Also, a tolerance on seed corn grain is not necessary, for it is covered by the field corn grain tolerance. We also note that tolerances for meat and milk may have to be revised in the future depending on the residue levels found in certain animal feed items.

Petitioner's Response to Deficiency #2a

The tolerance for corn forage has been revised to 6.0 ppm and the tolerances for sweet corn forage and seed corn grain have been deleted in the enclosed Section F.

CBTS Comments

A revised Section F has been submitted where a tolerance of 6.0 ppm for corn forage has been proposed, and the sweet corn tolerance has been deleted.

Deficiency #2a is resolved.

CBTS Deficiency #2b

Our 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.

Wheat hay is now considered to be a RAC. However, because tolerances for wheat forage and wheat straw are the same and lambda-cyhalothrin is not a systemic pesticide -- concentration of residues in the seed head does not occur -- the tolerance for wheat hay can be set at 2.0 ppm without submission of residue data. However, the petitioner should submit a revised Section B in which use directions for lambda-cyhalothrin in/on hay are proposed. In the meantime, tolerances can be established on the other wheat RACs (and the other RACs of PP#7F3560 -- sweet corn, sunflower with the exception of the sweet corn forage tolerances, which should be deleted from the Section F). The tolerance for hay should appear in the revised Section F (see next conclusion).

Petitioner's Response to Deficiency #2b

Zeneca agrees to conduct field residue trials for soybeans, grain sorghum and peanuts as specified by the Agency's comment for the purpose of generating residue data for soybean forage, soybean hay, grain sorghum forage, grain sorghum fodder, and peanut hay. Field trials for these crops can be carried out and reported over a 2 year period with the field portion in 1995 and the lab work during 1996. A proposed tolerance of

2.0 ppm for wheat hay has been included in the enclosed Section F. A revised Section B is enclosed which proposes use directions for lambda-cyhalothrin in/on wheat hay.

CBTS Comments

Deficiency #2b is resolved.

CBTS Deficiency #2c

CBTS has not reviewed a complete proposed Section F, since only a table of numerical tolerances has been submitted. All conclusions relating to these tolerances are therefore provisional. To be acceptable, the tolerance expression should include lambda-cyhalothrin and its epimer, and the nomenclature used should be the IUPAC names for these compounds. (The IUPAC names were given in our 3/23/92 memo for FAP#0H5599.) The petitioner should submit a complete Section F for our review that includes appropriate chemical names, a revised tolerance level for corn forage (see Conclusion 2a), and deletion of tolerances for sweet corn forage and seed corn grain. Although this Section F needs to address numerous petitions, it can be submitted as one document so long as the appropriate petition number is provided for each tolerance.

Petitioner's Response to Deficiency #2c

A revised Section F with the IUPAC nomenclature, and with the revised tolerance for corn forage, the deletion of sweet corn forage and seed corn grain tolerances, and the proposed tolerance for wheat hay, is enclosed.

CBTS Comments

Although the submitted Section F is adequate, the petitioner must be reminded that in M. Flood's memo of 5/16/94, CBTS recommended that proposed tolerance residues of lambda-cyhalothrin and its epimer in/on soybeans, peanuts and peanuts hulls, and sorghum grain and grain dust be established with an expiration date until residue data for soybean forage and hay, grain sorghum forage and fodder, and peanut hay are submitted to the Agency.

Deficiency #2c is resolved.

OTHER CONSIDERATIONS

The petitioner has submitted a proposal for amended use of Karate® on sunflowers to increase the number of applications per season from 3 applications/season to 4 applications/season.

Residue data originally submitted in support of a tolerance for sunflowers appear in V. F. Boyd's memo of 2/3/88. Eight residue trials were conducted in CO (2), KS (1), NE (1), ND (2), SD (1), and TX (1). Three applications of lambda-cyhalothrin were made by ground (5 trials) and by air (3 trials) with PHI's ranging from 43 to 47 days after the last application. The proposed label specified applications at a maximum of 0.09 lbs. ai/A/season (3 x 0.03 lbs. ai/A) with a PHI of 45 days. Tolerances of 0.05 ppm and 0.07 ppm for lambda-cyhalothrin and its epimer were proposed, based on the submitted data, on sunflower seed and sunflower hulls, respectively.

The proposed amended label specify the following directions for sunflowers: apply 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.

Currently, residue data reflecting the new application pattern of Karate® to sunflowers appear in the following report:

"Lambda-cyhalothrin (ICIA0321): Magnitude of the Residue Study on Sunflowers"; P. D. Francis; 3/3/94; Performing Laboratories were Huntingdon Analytical Services, Middleport, NY and Zeneca Ag Products, Richmond, CA (MRID# 432963-02).

Eight field trials on sunflowers were conducted, six in 1988 and 2 in 1990. The field trials were conducted in CA (1), ND (2), SD (1), CO (1), TX (2), and MN (1). According to Agricultural Statistics, 1988, these states represent nearly 100% of the sunflower production in the U.S. Three plots were used in each trial during 1988. Plot #1 was the untreated control and received only the maintenance spray applications. Plot #2 received the following applications: 1 - one application at the rate of 0.03 lbs. ai/A 5 days prior to emergence to 10 days after emergence; 2 - one application at the rate of 0.03 lbs. ai/A at 1 to 5% bloom stage; and 3 - one application at the rate of 0.03 lbs. ai/A 45 days before harvest. Plot #3 received the following applications: 1 - one application at 0.03 lbs. ai/A 5 days prior to emergence to 10 days after emergence; 2 - one application at 0.03 lbs. ai/A at 1 to 5% bloom stage; 3 - one application at 0.03 lbs. ai/A at 50% bloom stage; and 4 - one application at 0.03 lbs. ai/A 45 days before harvest. In the two trials conducted in 1990 only two plots were used: plot #1 as

the untreated control plot and plot #2 as the treated plot. Plot #2 received the same application regime as for plot #3 in the 1988 trials. Karate® was applied by ground equipment in the field trials conducted in 1988 and by air, in 2 gallons of water, in the 1990 field trials.

CBTS concludes that geographic representation of residue data is adequate for the proposed use on sunflowers.

Forage was sampled after one application at about six weeks after planting except in the 1988 Texas field trial where forage was sampled two days after the second application, and in the 1988 Colorado field trial where the forage was sampled forty five days after the last application. Seed samples were collected at maturity, 44 to 55 days after either the third or fourth application.

After collection, samples were frozen and shipped to the Eastern Research Center in Goldsboro, North Carolina for the trials conducted in 1988. These samples were subsequently shipped frozen to the Western Research Center in Richmond, California. The samples from the trials conducted in 1990 were frozen and shipped to the Western Research Center in Richmond, California.

Residues of lambda-cyhalothrin were shown to be stable when stored at -18°C for up to 26 months in commodities like peach, pea, oil seed rape, wheat grain, sugarbeet root, cottonseed, apple, cabbage and potatoes (PP#0H5599, M. Flood's memo of 9/19/91). Lambda-cyhalothrin metabolites (PP890, 3-PBAcid, 3-PBAcohol) have been shown to be stable in plant matrices under frozen storage for periods up to 36 months. Lambda-cyhalothrin and its epimer have been shown to be stable in processed commodities under frozen storage conditions for periods up to 34 months (M. Flood's memo of 5/16/94). Samples of sunflower seed and forage were analyzed for lambda-cyhalothrin residues up to almost 21 months after sampling. Maximum interval between extraction and analyses were 28 days for sunflower seed and 10 days for sunflower forage. Samples of sunflower seed and forage were analyzed for lambda-cyhalothrin metabolites PP890, 3-PBAcid and 3-PBAcohol up to almost 26 months after sampling. Maximum interval between extraction and analyses was 5 days for sunflower seed and 3 days for sunflower forage.

Recovery data were obtained from untreated samples of sunflower seed fortified with lambda-cyhalothrin at the level of 0.013 ppm to 2.1 ppm. Overall recoveries of 72% to 103% were obtained. Recovery data for lambda-cyhalothrin epimer at fortification levels of 0.017 ppm to 2.8 ppm were of 71% to 103%. Recovery data for metabolites PP890, 3-PBAcid, and 3-PBAcohol at fortification levels of 0.02 ppm to 0.10 ppm ranged from 66.8% to 75.8% for PP890, 86.2% for 3-PBAcid, and 88.2% for 3-PBAcohol. Recovery data were obtained from untreated samples of sunflower forage fortified with lambda-cyhalothrin at the level of 0.013 ppm to 2.1 ppm. Overall recoveries of 62% to 113% were obtained. Recovery data for lambda-cyhalothrin epimer at fortification levels of 0.017 ppm to 2.8 ppm were of 61% to 114%. Recovery data for metabolites PP890, 3-PBAcid, and 3-PBAcohol at fortification

levels of 0.05 ppm to 0.10 ppm ranged from 113.4% to 124.6% for PP890, 112.5% for 3-PBAcid, and 88.5% for 3-PBAcohol. Submitted chromatograms show well resolved peaks in support of this data.

Table I summarize the amount of residues on sunflower seed resulting from 3 or 4 applications of lambda-cyhalothrin at the rate of 0.03 lbs. ai/A.

Table I. Lambda-cyhalothrin Residues on Sunflower Seed

| Field Trial Location | No. of Applications | PHI | ICIA0321 (ppm) ¹ | R157836 (ppm) ² | PP890 (ppm) ³ | 3-PBAcid (ppm) ⁴ |
|----------------------|---------------------|-----|-----------------------------|----------------------------|--------------------------|-----------------------------|
| ND (1988) | | | | | | |
| | -- | -- | <0.01, <0.01 | <0.01, <0.01 | -- | -- |
| | 3 | 44 | 0.04 | <0.01 | -- | -- |
| | 4 | 44 | <0.01 | <0.01 | -- | -- |
| | | | | | | |
| ND (1990) | | | | | | |
| | -- | -- | <0.01 | <0.01 | -- | -- |
| | 4 | 45 | 0.03 | <0.01 | -- | -- |
| | | | | | | |
| SD (1988) | | | | | | |
| | -- | -- | <0.01 | <0.01 | <0.01 | <0.01 |
| | 3 | 55 | <0.01, <0.01 | <0.01, <0.01 | -- | -- |
| | 4 | 55 | <0.01 | <0.01 | <0.01 | <0.01 |
| | | | | | | |
| MN (1988) | | | | | | |
| | -- | -- | <0.01, <0.01 | <0.01, <0.01 | <0.01 | <0.01 |
| | 3 | 45 | 0.15 | 0.01 | -- | -- |
| | 4 | 45 | 0.07, 0.07 | <0.01, <0.01 | 0.01 | <0.01 |
| | | | | | | |
| TX (1988) | | | | | | |

| Field Trial Location | No. of Applications | PHI | ICIA0321 (ppm) ¹ | R157836 (ppm) ² | PP890 (ppm) ³ | 3-PBAcid (ppm) ⁴ |
|----------------------|---------------------|-----|-----------------------------|----------------------------|--------------------------|-----------------------------|
| | -- | -- | <0.01 | <0.01 | <0.01 | <0.01 |
| | 3 | 50 | 0.03 | <0.01 | -- | -- |
| | 4 | 50 | 0.06 | <0.01 | 0.01 | <0.01 |
| | | | | | | |
| TX (1990) | | | | | | |
| | -- | -- | <0.01 | <0.01 | -- | -- |
| | 4 | 45 | <0.01, <0.01 | <0.01, <0.01 | -- | -- |
| | | | | | | |
| CO (1988) | | | | | | |
| | -- | -- | <0.01, <0.01 | <0.01, <0.01 | <0.01 | <0.01 |
| | 3 | 45 | <0.01, <0.01 | <0.01, <0.01 | -- | -- |
| | 4 | 45 | <0.01 | <0.01 | <0.01, <0.01 | <0.01, <0.01 |
| | | | | | | |
| CA (1988) | | | | | | |
| | -- | -- | <0.01 | <0.01 | -- | -- |
| | 3 | 45 | <0.01 | <0.01 | -- | -- |
| | 4 | 45 | <0.01, <0.01 | <0.01, <0.01 | -- | -- |

1. Lambda-cyhalothrin

2. epimer of lambda-cyhalothrin

3. cis-isomer

4. 3-Phenoxybenzoic Acid (combination of 3-PBAcohol + 3-PBAcid)

The residue data presented above show maximum residues in seed of 0.15 ppm for ICIA0321, 0.01 ppm for R157836, 0.01 ppm for PP890 and <0.01 ppm for PBAcid.

Table II summarizes the amount of residues on sunflower forage resulting from 1 to 4 applications of lambda-cyhalothrin at the rate of 0.03 lbs. ai/A.

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Table II. Lambda-cyhalothrin Residues on Sunflower Forage

| Field Trial Location | No. of Applications | PHI | ICIA0321 (ppm) ¹ | R157836 (ppm) ² | PP890 (ppm) ³ | 3-PBAcid (ppm) ⁴ |
|----------------------|---------------------|-----|-----------------------------|----------------------------|--------------------------|-----------------------------|
| ND (1988) | | | | | | |
| | -- | -- | <0.01, <0.01 | <0.01, <0.01 | -- | -- |
| | 1 | 39 | <0.01 | <0.01 | -- | -- |
| | 1 | 39 | <0.01, <0.01 | <0.01, <0.01 | -- | -- |
| ND (1990) | | | | | | |
| | -- | -- | <0.01 | <0.01 | -- | -- |
| | 1 | 28 | <0.01 | <0.01 | -- | -- |
| SD (1988) | | | | | | |
| | -- | -- | <0.01 | <0.01 | <0.01 | <0.01 |
| | 1 | 50 | <0.01 | <0.01 | -- | -- |
| | 1 | 50 | <0.01 | <0.01 | <0.01 | <0.01 |
| MN (1988) | | | | | | |
| | -- | -- | <0.01, <0.01 | <0.01, <0.01 | <0.01 | <0.01 |
| | 1 | 42 | <0.01, <0.01 | <0.01, <0.01 | -- | -- |
| | 4 | 42 | <0.01 | <0.01 | <0.01 | <0.01 |
| TX (1988) | | | | | | |
| | -- | -- | <0.01 | <0.01 | <0.01 | <0.01 |
| | 2 | 2 | 0.71 | 0.08 | -- | -- |
| | 2 | 2 | 0.96 | 0.10 | 0.11, 0.11 | 0.03, 0.04 |
| TX (1990) | | | | | | |
| | -- | -- | <0.01 | <0.01 | -- | -- |
| | 1 | 26 | <0.01, <0.01 | <0.01, <0.01 | -- | -- |

| Field Trial Location | No. of Applications | PHI | ICIA0321 (ppm) ¹ | R157836 (ppm) ² | PP890 (ppm) ³ | 3-PBAcid (ppm) ⁴ |
|----------------------|---------------------|-----|-----------------------------|----------------------------|--------------------------|-----------------------------|
| CO (1988) | | | | | | |
| | -- | -- | <0.01, <0.01 | <0.01, <0.01 | <0.01 | <0.01 |
| | 3 | 45 | 0.05, 0.05 | <0.01, <0.01 | -- | -- |
| | 4 | 45 | 0.04 | <0.01 | 0.03 | 0.01 |
| | | | | | | |
| CA (1988) | | | | | | |
| | -- | -- | <0.01 | <0.01 | -- | -- |
| | 1 | 30 | <0.01 | <0.01 | -- | -- |
| | 1 | 30 | <0.01, <0.01 | <0.01, <0.01 | -- | -- |

1. Lambda-cyhalothrin

2. epimer of lambda-cyhalothrin

3. cis-isomer

4. 3-Phenoxybenzoic Acid (combination of 3-PBAcohol + 3-PBAcid)

Forage samples taken six weeks after planting with intervals between the first application and sampling ranging from 26 to 50 days showed no detectable residues (<0.01 ppm). The petitioner stated that the Texas and Colorado trials were deviations from the protocol. Lambda-cyhalothrin residues in/on the forage from the 1988 Texas trial were 0.96 ppm for ICIA0321, 0.10 ppm for R157836, 0.11 ppm for PP890, and 0.04 ppm for 3-PBAcid. Lambda-cyhalothrin residues in/on the forage from the 1988 Colorado trial were 0.05 ppm for ICIA0321, <0.01 ppm for R157836, 0.03 ppm for PP890, and 0.01 ppm for 3-PBAcid.

CBTS notes that in MRID#432963-02 there is a forage restriction that reads as follows: "Foraging is to be restricted to up to six weeks after a single application". However, this restriction does not appear in the proposed label. The petitioner needs to submit a revised Section B that includes the forage restriction in order to support the subject amended registration.

CBTS concludes that since, from cultural practice considerations, there is no apparent reason for residues in sunflower forage to be lower than in the seed, and that there is no assurance that forage treated more than one time with lambda-cyhalothrin will not be fed to animals, the tolerance level for sunflower forage will have to be set equal to sunflower seed. A revised Section F proposing a tolerance of 0.20 ppm for residues of lambda-cyhalothrin and its epimer in/on sunflower forage is needed.

TOX considerations permitting, and provided that a revised Section B with the forage restriction for sunflowers and a revised Section F proposing a tolerance of 0.20 ppm in/on sunflower forage are submitted, CBTS recommends that the following tolerance for residues of lambda-cyhalothrin and its epimer in/on sunflowers, seed and sunflower forage at 0.20 ppm be established.

Processing Studies

A sunflower processing study was reviewed in V. F. Boyd's memo of 2/3/88. A treated plot of sunflowers in TX received three foliar applications of Karate at 0.30 lbs. ai/A (10X the label rate). Sunflower samples were harvested 45 days after the last application.

Results are given in Table III.

Table III. Karate® Residues in Sunflower Processing Fractions

| Commodity | ICIA0321 (ppm) ¹ | R157836 (ppm) ² | Total Residues (ppm) |
|------------------------------------|--------------------------------|-------------------------------|----------------------------|
| Whole Seed | 0.24 | 0.04 | 0.28 |
| Hulls | 0.55 | 0.08 | 0.63 |
| Presscake | 0.04 | 0.01 | 0.05 |
| Crude Oil | 0.18 | 0.03 | 0.21 |
| Refined Oil | 0.03 | 0.17 | 0.20 |
| Soapstock | 0.01 | 0.02 | 0.03 |
| Refined Bleached Oil | 0.18 | 0.04 | 0.22 |
| Refined Bleached Deodorized Oil | 0.13 | 0.03 | 0.16 |
| Deodorizer Distillates | <0.01 | <0.01 | <0.01 |
| Solvent Extracted Presscake | 0.02 | <0.01 | 0.02 |
| Solvent Extracted Crude Oil | 0.36 | 0.05 | 0.41 |

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

Whole sunflower seeds containing 0.28 ppm yielded hulls containing 0.63 ppm, which is a concentration factor of 2.25X. Applying this concentration factor to the proposed tolerance of 0.20 ppm for sunflower seeds results in 0.45 ppm. Residues in solvent extract crude oil were 0.41 ppm, which is a concentration factor of 1.46X. Applying this concentration factor to the proposed tolerance of 0.20 ppm for sunflower seeds results in 0.30 ppm.

TOX considerations permitting, and provided that a revised Section B and F are submitted for sunflowers, CBTS recommends that the following tolerances for lambda-cyhalothrin and its epimer in/on sunflower, hulls at 0.50 ppm; sunflower, oil at 0.30 ppm be established.

MEAT, MILK, POULTRY AND EGGS

We expect no increase in the dietary burden of poultry and ruminants as a result of this use. Therefore, CBTS anticipates that any secondary residues that might result in milk, meat, poultry, and eggs would be covered by the proposed tolerances on these commodities.

cc: RF, Circu., José J. Morales, M. Flood, E. Haeberer, PP#'s 7F3560/7H5543; 7F3488; 1F3952/1H5607; 1F3992; 2F4100; 2F4114; 1F3985
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