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OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP No. 5E4431. Lambda-Cyhalothrin (128897; Karate[®]) on Imported Cucurbits and Sweet Peppers. Evaluation of Residue Data and Analytical Methodology. MRID No. 43421701, 43421702, 43421703, 43421704, 43421705, 43421706, 43421707, 43421708, 43421709, 43488002. D210688. Case No. 286055.

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Zeneca Ag Products is requesting the establishment of tolerances for the insecticide lambda-cyhalothrin on the crop group cucurbits, and sweet peppers at 0.05 ppm and 0.1 ppm, respectively, grown in Mexico and Central America. The establishment of these requested tolerances would allow their legal import into the United States.

Tolerances with an expiration date of November 15, 1997 are established in 40 CFR §180.438 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 (1S)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)- α -cyano-3-phenoxybenzyl (1R)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate) on several raw agricultural commodities (RACs) at levels ranging from 0.01 to 0.25 ppm. Several other RAC tolerances are pending (wheat, sweet/pop/field/seed corn, peanuts, onions, garlic, and sunflowers). A food additive tolerance of 10.0 ppm in/on dried

hops is established under 40 CFR §185.1310 as a result of FAP#0H5599 (57 FR 32440).

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

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

Conclusions

- 1a. The manufacturing process of technical grade lambda-cyhalothrin has been adequately described. CBTS does not foresee any residue problems from impurities in the technical.
- 1b. Since the end use products which are used on cucurbits and sweet peppers in the countries of origin may differ from those registered in the United States and the products are not subject to U.S. regulation, the petitioner must verify that the inert ingredients used in these products are cleared for use on crops.
2. The petitioner has submitted labels for Mexico, Guatemala and Costa Rica. It is recommended that the labels be amended to specify the intervals (days) between application, and a maximum seasonal application rate so as to avoid the potential for over tolerance residue levels (see also conclusion 5a).
3. The nature of the residue in plants is adequately understood. The residue to be regulated is lambda-cyhalothrin, and its epimer. Since no animal feed items are associated with RACs in the cucurbit crop group and sweet peppers, the nature of the residue in livestock is not an issue related to this petition.
- 4a. ICI Method 81 for parent lambda-cyhalothrin and its epimer in plant matrices has undergone successful EPA method validation.
- 4b. Recoveries have been determined using FDA's multiresidue protocols for cyhalothrin, and thus this requirement has been met for lambda-cyhalothrin (see PP#7F3488, S. Willett's memo of 3/15/88; PP#7F3560/7H5543, M. Flood's memo of 9/19/91).
- 5a. The submitted residue data are adequate in quantity, quality and location to support the proposed tolerances on cucurbits and sweet peppers as long as the treatment schedules for these crops are limited to a total of 4 applications of 35 g ai/ha, or 10 applications of 15 g ai/ha per season. Storage

stability data have been previously reviewed which support the validity of these residue study data.

- 5b. There are no human foods or animal feed items derived from the processing of cucurbit vegetables or sweet peppers, thus no food or feed additive tolerances are needed in association with the proposed RAC tolerances.
6. Since no animal feed items are associated with RACs in the cucurbit crop group and sweet peppers, the adequacy of tolerances in domestic animal commodities is not an issue that is related to this petition.
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 cucurbits or sweet peppers, no compatibility problems exist.

Recommendations

TOX considerations permitting, CBTS recommends for the proposed tolerances for lambda-cyhalothrin at 0.05 ppm on cucurbits and 0.1 ppm on sweet peppers provided the treatment schedule as discussed in conclusion 5a above is utilized. **A DRES run can be initiated at this time.**

Detailed Considerations

Product Chemistry

The manufacturing process for technical grade lambda-cyhalothrin has been previously described in support of domestic registrations, and has been determined to be adequate (see PP#6F3318, MRID# 401820-02, S. Brooks' memo of 9/29/87). There are no concerns for any of lambda-cyhalothrin impurities. Discussion about structure and isomers appears in M. Flood's memo of 9/19/91 (PP#7F3560/7H5543).

Proposed Use

The petitioner has submitted draft labels and english translations of labels from end use products to be used in Mexico, Guatemala, and Costa Rica. For control of the armyworm, white fly, aphid, leafminer, salt marsh caterpillar, and melon/cucumber caterpillar in cucurbit vegetables, and the fruit borer, leafminer, lesser army worm, and cabbage looper in sweet peppers grown in Mexico, the

proposed application rates vary according to location. A summary the use rates and conditions is provided in the table that follows.

TABLE 1: PROPOSED USES OF LAMBDA-CYHALOTHRIN ON CUCURBITS AND SWEET PEPPERS IN MEXICO, GUATEMALA AND COSTA RICA

RAC	LOCATION	G AI/L END USE PRODUCT	AMT/APP.	MAX APPS/CYCLE	PHI (DAYS)	APP. INTERVAL	APP. EQUIP.
CUCURBITS	MEXICO	65	0.5 L/HA (32.5 G AI/HA)	N/S	7	N/S	G
CUCURBITS	GUATEMALA COSTA RICA	83.3	120-150 CC/HA (12.5 G AI/HA)	4 (50 G AI/HA)	7	N/S	G
SWEET PEPPERS	MEXICO	65	0.5 L/HA (32.5 G AI/HA)	N/S	7	N/S	G, A

N/S = NOT SPECIFIED G = GROUND EQUIPMENT (MINIMUM 200 L/HA) A = AERIAL EQUIPMENT (MINIMUM 40 L/HA)

It is recommended that treatment intervals and maximum seasonal application rates should be specified on the label so that the potential for over tolerance residue levels can be minimized. See also the Residue Data section below.

Nature of the Residue

The nature of the residue in plants is adequately understood. The residue to be regulated is lambda-cyhalothrin, and its epimer (see PP No. 7F3560/7H5543). Since no animal feed items are associated with RACs in the cucurbit crop group and sweet peppers, the nature of the residue in domestic animals is not an issue related to this petition.

Analytical Methodology

Analytical methodology is available for enforcement of the proposed tolerances. ICI Method 81 for parent lambda-cyhalothrin and its epimer in plant matrices has undergone successful EPA method validation. 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 (PP#6F3318/PP#7F3488, E. Greer memo of 9/30/87).

Recoveries have been determined using FDA's multiresidue protocols for cyhalothrin, and thus this requirement has been met for lambda-cyhalothrin (see PP#7F3488, S. Willett's memo of 3/15/88; PP#7F3560/7H5543, M. Flood's memo of 9/19/91).

Residue Data

(MRID Nos. 434217-01 thru -09, 434880-02)

Residue trials were carried out in Costa Rica (4), Guatemala (8), and Mexico (17 on cucurbits; 6 on sweet peppers) during 1992 and 1993. Foliar applications of lambda cyhalothrin formulated as a 7EC (Mexico) and a 8.33EC (Guatemala and Costa Rica) at rates of 140 g ai/ha (35 g ai X 4 applications in Mexico; 1.25 lbs ai/acre), and 150 g ai/ha (10 g ai X 15 applications in Guatemala and Costa Rica; 1.34 lbs/acre) were made using ground equipment in volumes of 200 to 600 L/ha (130 to 391 US gals/acre). Treatment intervals ranged from 2 to 7 days. Samples for residue analyses were harvested 7 days after the last application in all trials, except one trial on melons conducted in Costa Rica, where the PHI was 8 days. After harvest, all samples were stored frozen, and analyzed within 11 months. Residues of lambda-cyhalothrin were shown to be stable when stored at -18°C for up to 36 months in a variety of commodities (see 9/19/91 and 5/16/94 memos of M. Flood).

Whole samples of the various commodities were analyzed (single analysis per sample) using Zeneca method SOP RAM/081/01, which is the enforcement method previously described. The limit of determination for the method is 0.01 ppm. All residue analyses were conducted by the Zeneca Agrochemicals laboratory at Jealotts Hill Research Station, Berkshire UK, according to current U.S. GLP requirements. Recovery samples were analyzed concurrently with residue samples, and recoveries were acceptable ($\geq 70\%$). Control samples had no detectable residues. Supporting information (e.g. sample handling history, application history, sample chromatograms) were included in the residue reports. A summary of the residue data is provided in table 2.

TABLE 2: RESIDUE LEVELS OF LAMBDA-CYHALOTHRIN AND ITS EPIMER IN CUCURBITS AND SWEET PEPPERS FROM TRIALS CONDUCTED IN MEXICO, COSTA RICA, AND GUATEMALA

CROP	TRIAL LOCATION	# OF TRIALS	# OF APPS. X G A.I.	TOTAL A.I. APPLIED, G/HA	PPM PARENT	PPM EPIMER
SQUASH	MEXICO	7	4 X 35	140	<0.01-0.01	<0.01
	GUATEMALA	3	10 X 15	150	<0.01-0.03	<0.01
	COSTA RICA	2	10 X 15	150	<0.01	<0.01
CUCUMBER	MEXICO	5	4 X 35	140	<0.01-0.02	<0.01-0.02
	GUATEMALA	2	10 X 15	150	<0.01-0.02	<0.01
MELON	MEXICO	5	4 X 35	140	<0.01-0.02	<0.01
	GUATEMALA	3	10 X 15	150	0.01-0.02	<0.01
	COSTA RICA	2	10 X 15	150	0.01, 0.01	<0.01
SWEET PEPPERS	MEXICO	6	4 X 35	140	0.01-0.09	<0.01-0.01

CBTS concludes that the residue data are adequate in quantity, quality and location to support the proposed tolerances on cucurbits and sweet peppers as long as the treatment schedules for these crops are limited to a total of 4 applications of 35 g ai/ha, or 10 applications of 15 g ai/ha per season.¹

There are no human foods or animal feed items derived from the processing of cucurbit vegetables or sweet peppers, thus no food or feed additive tolerances are needed in association with the proposed RAC tolerances.

Secondary Residues in Meat, Milk, Eggs and Poultry

Since no animal feed items are associated with RACs in the cucurbit crop group and sweet peppers, the adequacy of tolerances in livestock commodities is not an issue related to this petition.

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 cucurbits or sweet peppers, no compatibility problems exist.

¹Per guidance published in Pesticide Guidance Document EPA 738-K-94-001, June 1994, and 11/95 draft internal guidance on import tolerance data requirements.

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Attachment: International Residue Limit Status Sheet

cc: George LaRocca/Linda Deluise (PM 13), RF, Circ, S. Willett, E. Haeberer, PP No 5E4431

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RDI: E. Haeberer, 5/31/96; R. Perfetti, 6/3/96; E. Zager, 6/3/96



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