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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4F3136 (RCB No. 884) Permethrin on Collards, Mustard Greens, and Turnip Greens - Evaluation of Amendment Dated March 12, 1986 (Accession No. 261896)

FROM: Michael P. Firestone, Ph.D., Chemist
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Hazard Evaluation Division (TS-769C)

TO: George LaRocca, PM 15
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Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

ICI Americas, Inc. has submitted this amendment, consisting of revised Sections B and F and supplemental data, in response to several deficiencies cited in the Residue Chemistry Branch (RCB) review of the original petition for a permethrin crop group (V) tolerance on Brassica (cole) leafy vegetables (see M. Firestone memorandum of December 26, 1984 re: PP#4F3136).

With submission of the current (March 12, 1986) amendment, ICI has replaced its request for a crop group tolerance for Brassica (cole) leafy vegetable raw agricultural commodities (rac's) and is now requesting individual permethrin tolerances for collards at 15 parts per million (ppm), and mustard greens and turnip greens at 20 ppm.

In conjunction with PP#6E3360, Interregional Research Project No. 4 (IR-4) submitted a petition requesting permethrin tolerances for collards, mustard greens, and turnip greens all at 20 ppm, and turnip roots at 1 ppm (see N. Dodd memorandum of April 16, 1986); this petition is currently in reject status.

Deficiencies cited in RCB's December 26, 1984 review of PP#4F3136 (the subject petition) will be restated below, followed by the petitioner's responses and RCB's comments/ conclusions.

Deficiency 1a

According to 40 CFR 180.34(f):

> If maximum residues (tolerances) for the representative crops vary by more than a factor of 5 from the maximum value observed for any crop in the group, a group tolerance will ordinarily not be established. In this case, individual crop tolerances, rather than group tolerances, will normally be established.

The representative crops of group V (Brassica [Cole] Leafy Vegetables) include broccoli, cabbage, and mustard greens for which established or proposed permethrin tolerances are 1 ppm, 6 ppm, and 20 ppm, respectively. Since these tolerances vary by a factor of 20, the petitioner should seek establishment of individual tolerances (i.e., submit a revised Section F) for rac's of crop group V. All comments and conclusions expressed in this review should be considered prior to a request for the establishment of individual tolerances.

ICI's Response

A revised Section F has been submitted in which individual tolerances are proposed for collards at 15 ppm and mustard greens and turnip greens at 20 ppm.

RCB's Comments/Conclusions re: Deficiency 1a

The numerical adequacy of the above proposed tolerances will be considered under Deficiencies 4b (mustard greens), 4c (collards), and 4e (turnips). However, since individual tolerances are now proposed, Deficiency 1a is considered resolved.

Deficiency 1b

Section B/label should be revised so that the crops to be treated include individual crops, not groups such as "leafy vegetables."

ICI's Response

A revised Section B/label has now been submitted.

The crops to be treated include collards, turnip greens, and mustard greens. The application rate remains 0.05 to 0.1 lb ai/A. The revised label allows for a maximum of eight applications (presumably per crop season). Permethrin can be applied up to the day of harvest (i.e., PHI = 0 days).

Label restrictions include:

1. Apply by ground equipment using sufficient water to obtain uniform coverage; and

2. Do not graze treated areas or feed crop refuse to livestock.

RCB's Comments/Conclusions re: Deficiency 1b

The petitioner should revise Section B/label to clarify that permethrin should be applied by ground equipment only, and that the maximum number of applications per crop season is eight.

If the petitioner wants to maintain a zero-day PHI, any additional residue data should reflect such a PHI or Section B/label should be revised with regard to the proposed PHI.

Thus, Deficiency 1b remains pending at this time.

Deficiency 3a

Analytical method GRAM-1/I was used for the determination of permethrin (parent compound only) residue data submitted in this petition. A version of this method has passed EPA method trial. The petitioner will need to submit the following before RCB can make any conclusion concerning the adequacy of method GRAM-1/I to generate permethrin (parent compound only) residue data:

1. A discussion of how the 78 percent (spinach) and 92 percent (mustard) recovery values were calculated. According to the raw data sheets, these values actually appear to be 106 percent and 124 percent, respectively.

2. Raw data sheets for ICI Report TMU1317/B (reference 4D).

3. A description of which greens were fortified in conjunction with ICI Report TMU1317/B (this information is probably included in the raw data sheets requested above).

ICI's Response

1. "Both of these recoveries were from samples spiked at the limit of determination (0.05 ppm). In each case, the control sample that was spiked contained what appeared to be some detectable residue of permethrin but in a concentration below the limit of determination. This small amount of background had a significant effect on these low concentration recoveries so the analyst estimated the residue concentrations in the controls using the peak height method of calculation and then subtracted that value from the value obtained from the spike sample."

   The petitioner has also submitted calculations to demonstrate how the various values were calculated.

2/3. Raw data sheets for ICI Report TMU1317/B (including a description of which greens were fortified) have been submitted as Reference 9-1 of the IR-4 petition PP#6E3360.

RCB's Comments/Conclusions re: Deficiency 3a

1. The petitioner has adequately explained the discrepancy in the calculation of recovery values.

2/3. Fortification/recovery data for permethrin using method GRAM-1/I were generated on kale, mustard greens, and turnips.

RCB concludes that Deficiency 3a has been resolved.

Deficiency 3b

Methods GRAM-5/2 and -5/3 were used to generate the DCVA and 3-PBAlc residue data submitted in this petition. A version of these methods has successfully passed EPA method trial.

RCB can reach no final conclusion concerning the adequacies of methods GRAM-5/2 and -5/3 to generate permethrin metabolite (DCVA and 3-PBAlc) residue data on Brassica (cole) leafy vegetables until the petitioner submits raw data sheets for ICI Report TMU1319/B (reference 5D) including information concerning which greens were used to generate the submitted fortification-recovery data.

ICI's Response

Raw data sheets for ICI Report TMU1319/B have been submitted as Reference 9-2 of the IR-4 petition PP#6E3360.

RCB's Comments/Conclusions re: Deficiency 3b

Fortification/recovery data were generated on kale, mustard greens, turnips, spinach, and collard greens.

RCB concludes that Deficiency 3b has been resolved.

Deficiency 4a

Permethrin-treated Brassica crop samples upon which the residue data submitted in this petition were generated had been stored frozen up to 49 months before analysis. The petitioner should submit storage stability data which show that residues of permethrin and its metabolites (DCVA and 3-PBAlc) are stable for up to 49 months under frozen conditions (preferably in a Brassica leafy vegetable).

ICI's Response

Storage stability data reflecting sorghum stored at -10 °F for 52 months has been submitted as Reference 9-3 of the IR-4 petition PP#6E3360; permethrin and its metabolites are reportedly stable under these conditions of storage.

RCB's Comments/Conclusions re: Deficiency 4a

Based on the above storage stability data, and additional data reflecting storage of several Brassica leafy vegetables (turnips, mustard greens, and collard greens) for 7 to 9 months, RCB previously concluded in conjunction with its review of PP#6E3360 that adequate storage stability data have been submitted to support the proposed permethrin use on collards, mustard greens, and turnips (see N. Dodd memorandum of April 16, 1986).

Thus, RCB concludes that Deficiency 4a is now resolved.

Deficiency 4b

The limited amount of residue data on treated mustard greens reportedly show that four applications at the maximum proposed rate will not result in total permethrin residues (parent plus DCVA and 3-PBAlc) exceeding the proposed 20 ppm tolerance. However, geographical representation is not adequate. The petitioner will need to submit additional residue data generated on treated mustard greens grown in the States of FL and either MI, OH, or IN. These data should reflect a minimum of nine applications at a rate of at least 0.1 lb ai/A with final treatment at the day of harvest.

ICI's Response

Additional data generated on mustard green samples grown in the States of WA and SC have been submitted as References 4 and 7 of the IR-4 petition PP#6E3360.

RCB's Comments/Conclusions re: Deficiency 4b

Based upon review of all mustard greens residue data including the above additional WA and SC residue data in conjunction with PP#6E3360 (see N. Dodd memorandum of April 16, 1986), RCB previously concluded the following:

> Geographic representation is not adequate for mustard greens. Additional residue data from FL and from MI, OH, or IN are needed. These data should reflect the maximum number of applications intended at the rate of 0.1 lb ai/A and the proposed 0-day PHI. Of the limited data which are available, the data from GA (four applications at the rate of 0.1 lb ai/A showing residues of 17.11 ppm) indicate that the number of applications may have to be limited to four so that the 20 ppm proposed tolerance is not exceeded . . . .

Thus, RCB concludes that Deficiency 4b has not been resolved.

Deficiency 4c

The highest reported total permethrin residue level on treated collards (11.27 ppm) resulted from seven applications at a rate of 0.1 lb ai/A. The limited amount of submitted residue data (two trials only) suggest that a tolerance of 15 ppm would be more appropriate than the proposed tolerance of 20 ppm. However, the petitioner will need to submit

additional residue data reflective of the maximum proposed use (i.e., at least nine applications up to the day of harvest at a rate of 0.1 lb ai/A) generated from field trials conducted in FL and one other Southeast or Gulf State before a final conclusion may be drawn.

ICI's Response

IR-4 has generated collard residue data on samples grown in the States of Washington and South Carolina.

RCB's Comments/Conclusions re: Deficiency 4c

In the Washington field trial, seven ground applications were made at 7- to 9-day intervals. In the South Carolina study, five ground applications were made at 6- to 8-day intervals. The shortest PHI was one day (note: the proposed PHI is 0 days; the maximum proposed number of allowable applications is eight).

RCB continues to conclude that the petitioner will need to submit additional residue data reflective of the maximum proposed use (i.e., at least eight applications up to the day of harvest (i.e., PHI = 0 days) at a rate of 0.1 lb ai/A) generated from field trials conducted in FL and one other Southeast or Gulf State before a final conclusion may be drawn.

Thus, Deficiency 4c has not been resolved.

Deficiency 4d

Residue data on kale were generated from only one field trial. This is considered inadequate to evaluate the proposed 20 ppm tolerance. The petitioner will need to conduct additional field trials in the States of VA and NY reflective of the maximum proposed use (i.e., nine applications up to the day of harvest at a rate of 0.1 lb ai/A).

ICI's Response

A tolerance is not proposed for kale in the revised Section F.

RCB's Comments/Conclusions re: Deficiency 4d

Deficiency 4d is considered resolved with submission of the revised Section F.

Deficiency 4e

Although turnips are considered a Brassica vegetable in terms of phylogeney, for the purpose of 40 CFR 180.34f, turnip greens are included in crop group II (Leaves of Root and Tuber Vegetables) not crop group V (Brassica-cole-Leafy Vegetables). However, since RCB is recommending that the petitioner seek permethrin tolerances on individual crops, the residue data on turnip greens have been evaluated in this review in support of a permethrin tolerance. If the petitioner desires a permethrin tolerance on turnip greens, residue data and a tolerance proposal will also be needed for permethrin on turnip roots.

Six permethrin applications at the maximum proposed rate reportedly resulted in a total permethrin residue level (0-day PHI) of 15.51 ppm, below the proposed tolerance of 20 ppm. However, geographical representation is considered inadequate. Since turnips are grown in every State (see Fruit and Vegetable Facts and Pointers of the United Fresh Fruit and Vegetable Association - 1973), the petitioner will need to submit additional residue data generated on permethrin-treated turnip greens and roots from field trials conducted in the States of CA, TX, and IL. These data should reflect the maximum proposed application (i.e., nine applications up to the day of harvest at a rate of 0.1 lb ai/A).

ICI's Response

Turnip roots residue data generated from field trials conducted in the States of Indiana, Texas, Washington, and South Carolina, and additional turnip greens residue data generated from Indiana, Texas, and Washington field trials have been submitted by IR-4 in PP#6E3360.

RCB's Comments/Conclusions re: Deficiency 4e

The additional turnip residue data have been reviewed by RCB in conjunction with PP#6E3360.

The turnip root data reflect four to eight applications with PHI's of 1, 3, and 5 days (note: minimum proposed PHI = 0 days; maximum number of applications at 0.1 lb ai/A rate = 8). Some of the data reflect parent compound only (SC and WA field trials). Maximum residues reflecting the maximum proposed application rate of 0.1 lb ai/A were as high as 0.25 ppm in turnip roots.

The petitioner will need to submit additional turnip roots residue data generated from samples grown in the State of California, and also Texas if a 0-day PHI is desired.

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Also, a tolerance will need to be proposed for permethrin (parent plus metabolites) in turnip roots.

The additional turnip tops residue data do not reflect a zero-day PHI. The Indiana and Texas data will support a 20 ppm turnip greens tolerance provided the proposed PHI is revised from zero to 1 day.

Additional residue data for turnip tops must be generated from samples grown in the State of California reflecting the maximum proposed use and minimum proposed PHI.

At this time, Deficiency 4e has not been resolved.

Other Considerations

An International Residue Limit Status sheet is included with this review as Attachment 1.

Since Codex, Canada, and Mexico have not established permethrin limits/tolerances for collards, mustard greens, and turnip greens, there are no compatibility problems.

Recommendations

At this time, RCB recommends against the proposed permethrin tolerances for collards, mustard greens, and turnip greens for the reasons cited under Deficiencies 1b, 4b, 4c, and 4e above.

Attachment 1: International Residue Limit Status Sheet

cc: R.F., Circu, M.P. Firestone, N. Dodd, EAB, EEB, PMSD/ISB, FDA, PP#4F3136, PP#6F3360
RDI:J.H. Onley-5/21/86:R.D. Schmitt-5/22/86
RCB:TS-769:M.P. Firestone:CM#2:Rm800b:557-1991
typed by KENCO:6/4/86:edited by mpf-6/5/86

Attachment 1

F. Hines 5/8/86

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: permethrin

PETITION NO.: PP#4F3136

CCPR NO.: 120

REVIEWER: Michael P. Firestone

Codex Status

☐ No Codex Proposal Step 6 or above

Residue (if Step 9): permethrin (sum of isomers)

Crop(s)	Limit (mg/kg)
none (on given crops	

Proposed U.S. Tolerances

Residue: permethrin, DCVA, 3-PBAlc

Crop(s)	Tol. (ppm)
collards	15
mustard greens	20
turnip greens	20

CANADIAN LIMIT

Residue: 3-phenoxy (±) cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate

Crop(s)	Limit (ppm)
turnips	0.1 !!

MEXICAN TOLERANCIA

Residue:

Crop(s)	Tolerancia (ppm)
none	

Notes: !! Negligible residue type limit