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OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6E3440 (RCB No. 2541). Diazinon on Chinese Radish (Roots and Tops). Amendment dated June 24, 1987.

FROM: Nancy Dodd, Chemist *Nancy Dodd*  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769C)

THRU: John H. Onley, Ph.D., Section Head *John H. Onley*  
Tolerance Petition Section II  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769C)

TO: Hoyt Jamerson, PM #43  
Registration Support and Emergency Response Branch  
Registration Division (TS-767C)

and

Toxicology Branch  
Hazard Evaluation Division (TS-769C)

The petitioner, IR-4, has now submitted an amendment to PP#6E3440. This amendment consists of a letter dated June 24, 1987, revised Sections B and F, and additional information concerning the analytical method. This amendment is submitted in response to deficiencies listed in RCB's review of PP#6E3440 dated December 2, 1986 (N. Dodd).

Conclusions

Note: All deficiencies are given in the Detailed Considerations Section that follows in this review.

1. Deficiency No. 2 is resolved. The method that the petitioner used to obtain residue data on Chinese radish is a combination of methods in PAM-I and PAM-II and is sufficiently similar to the AOAC method; therefore, further validation data for the minor crop Chinese cabbage is not required.

2. Deficiency No. 3 is resolved by submission of the storage temperature for the storage stability data. Storage stability data are adequate.
3. Deficiency No. 4a is resolved by submission of the revised Sections B and F, which restrict use to the states of California and Florida only.
4. Deficiency No. 4b is resolved by submission of the revised Section B/label which indicates that application should be made in a minimum of 100 gals. water per acre.
5. Deficiency No. 4c is resolved by submission of the revised Section B/label which indicates that applications should be made at 14-day intervals.
6. Deficiency No. 4d is resolved by resolution of issues relating to the analytical methodology. The proposed 0.1 ppm diazinon tolerance on Chinese radish (roots and tops) is adequate to cover residues resulting from the proposed use.
7. An International Residue Limits (IRL) Status sheet was attached to RCB's review of PP#6E3440 dated December 2, 1986. There are no specific Codex, Canadian, or Mexican tolerances for Chinese radish. However, there is a Codex proposal of 0.5 ppm for diazinon (fat-soluble residue) in vegetables (except leafy vegetables and sweet corn). There is a Canadian tolerance for diazinon on radishes at 0.25 ppm. There is a Mexican tolerance for diazinon on radishes at 0.75 ppm. The 0.1 ppm proposed U.S. tolerance for Chinese radish is lower than the Codex vegetable tolerances and also lower than the Canadian and Mexican radish tolerances. The tolerance expression for the United States (which now includes only parent) is different than for Codex (which includes fat-soluble residue) but the same as for Mexico and Canada.

#### Recommendation

If TB and EAB considerations permit, RCB recommends for the proposed 0.1 ppm tolerance for diazinon on Chinese radish.

#### Detailed Considerations

The deficiencies listed in the December 2, 1986 review of PP#6E3440 are outlined below, followed by the petitioner's responses and RCB's discussions/conclusions.

RCB's Deficiency No. 2

The petitioner should reanalyze some of his reserve field and storage stability samples (corresponding to the storage time of the reserve field samples) using the GLC method in Official Methods of Analysis - AOAC 29.001, 14th edition, 1984. This method can be used as a confirmatory or an alternative method to determine the residue of diazinon (see the Analytical Method section of this review for further details).

Petitioner's Response to Deficiency No. 2

The petitioner used petroleum ether for extraction and gas chromatography on 10% DC-200 columns for quantitative determination. The petitioner indicates that this method is based on principles of PAM-II and PAM-I chemistry:

- o The PAM-II method uses petroleum ether for extraction.
- o The PAM-I method uses gas chromatography with a 10% DC-200 glass column.

The petitioner has submitted a revised page 1 of the Minor Use Residue form to indicate that both PAM-I and PAM-II are sources of the analytical method.

The petitioner has indicated in a phone conversation with Frank Boyd of RCB that the method they used is similar to the GC method in Official Methods of Analysis - AOAC 29.001 to which RCB referred. (The AOAC method involves extraction of residues into CH<sub>3</sub>CN and then into petroleum ether. After cleanup on a Florisil column, residues are determined by GC and combinations of gas, thin layer, and paper chromatography.)

RCB's Discussion/Conclusion No. 2

Deficiency No. 2 is resolved. The method that the petitioner used to obtain residue data on Chinese radish is a combination of methods in PAM-I and PAM-II, and is sufficiently similar to the AOAC method; therefore, further validation data for the minor crop Chinese cabbage is not required.

RCB's Deficiency No. 3

The storage temperature must be specified before RCB can conclude that storage stability data are adequate for the present petition. The need for storage stability data is listed as a deficiency in the Residue Chemistry Chapter of the Diazinon Registration Standard.

Petitioner's Response to Deficiency No. 3

The petitioner indicates in the letter dated June 24, 1987 that samples were stored at -10 °C until analysis.

RCB's Conclusion No. 3

Deficiency No. 3 is resolved by submission of the storage temperature for the storage stability data. Storage stability data are adequate.

RCB's Deficiency No. 4a

The petitioner needs to submit a revised Section F requesting diazinon tolerances with regional registration of 0.1 ppm and a proposed use in the states of California and Florida only. Alternatively, additional residue data representing other radish-growing areas such as Michigan, Ohio, and Washington should be submitted to provide adequate geographical representation.

Petitioner's Response to Deficiency No. 4a

The petitioner has submitted a revised Section B/label (revised June 1987), which indicates that use is limited to the states of California and Florida only. The petitioner has also submitted a revised Section F (revised June 1987) with the following phrase added:

"Tolerances with regional registration:  
For use in California and Florida only."

RCB's Conclusion No. 4a

Deficiency No. 4a is resolved by submission of the revised Sections B and F which restrict use to the states of California and Florida only.

RCB's Deficiency No. 4b

A revised Section B/label should be submitted which specifies application in at least 100 gal water/A (rather than 10) since available residue data are obtained using 100 gal water/A. Alternatively, additional residue data using 10 gal water/A could be provided.

Petitioner's Response to Deficiency No. 4b

The petitioner has submitted a revised Section B/label (revised June 1987) which indicates that application should be made in a minimum of 100 gal water/A.

RCB's Conclusion No. 4b

Deficiency No. 4b is resolved by submission of the revised Section B/label which indicates that application should be made in a minimum of 100 gal water/A.

RCB's Deficiency No. 4c

The Section B/label should be revised to specify 14-day intervals between applications rather than 7- to 14-day intervals (based on available residue data with 6- and 8-day intervals in one study and 14- and 18-day intervals in the second study). Alternatively, additional residue data with approximately 7-day intervals should be provided for Florida or a specific interval designated on the label for each state, one for Florida and another one for California.

Petitioner's Response to Deficiency No. 4c

The petitioner has submitted a revised Section B/label (revised June 1987) which indicates that applications should be made at 14-day intervals.

RCB's Conclusion No. 4c

Deficiency No. 4c is resolved by submission of the revised Section B/label which indicates that applications should be made at 14-day intervals.

RCB's Deficiency No. 4d

RCB will reserve its conclusion on the adequacy of the proposed 0.1 ppm diazinon tolerance on Chinese radish until the issues relating to the analytical methodology have been resolved.

Petitioner's Response to Deficiency No. 4d

Refer to the petitioner's response to deficiency #2.

RCB's Conclusion No. 4d

Deficiency No. 4d is resolved by resolution of issues relating to the analytical methodology. RCB concludes that the proposed 0.1 ppm diazinon tolerance on Chinese radish (roots and tops) is adequate to cover residues resulting from the proposed use.

Other Considerations

An International Residue Limits (IRL) Status sheet was attached to RCB's review of PP#6E3440 dated December 2, 1986. There are no specific Codex, Canadian, or Mexican tolerances for Chinese radish. However, there is a Codex proposal of 0.5 ppm for diazinon (fat-soluble residue) in vegetables (except leafy vegetables and sweet corn). There is a Canadian tolerance for diazinon on radishes at 0.25 ppm. There is a Mexican tolerance for diazinon on radishes at 0.75 ppm. The 0.1 ppm proposed U.S. tolerance for Chinese radish is lower than the Codex vegetable tolerances and also lower than the Canadian and Mexican radish tolerances. The tolerance expression for the United States (which now includes only parent) is different than for Codex (which includes fat-soluble residue) but the same as for Mexico and Canada.

cc: RF, Circu, Reviewer-N. Dodd, PP#6E3440, PMSD/ISB-Eldredge,  
PM #43, TOX

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