PP#1F3995

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

DEC 16 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#1F3995 (CBTS #14733; Barcode #D209669). Fenbuconazole on Pecans. Amendment dated 11/14/94. (MRID #'s 434500-00 and 434500-01).

FROM: Nancy Dodd, Chemist Nancy Dodd
Tolerance Petition Section II
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

THROUGH: Richard Loranger, Ph.D., Acting Chief E. T. Haebere for 12/16/94
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

TO: Cynthia Giles-Parker, PM #22
Herbicide-Fungicide Branch
Registration Division (7505C)

and

Albin Kocialski, Section Head
Registration Section
Chemical Coordination Branch
Health Effects Division (7509C)

Rohm and Haas Company has responded to fenbuconazole reviews of PP#1F3995 on pecans (N. Dodd, 10/25/94, CBTS #13774, Barcode #D203653; and N. Dodd, 10/25/94, CBTS #14546, Barcode #D208444). This amendment contains a letter dated 11/14/94 (MRID #434500-00), hand-written revisions to the Enable 2F label, and a revised analytical method for fenbuconazole and its metabolites RH-9129, RH-9130, and RH-6467 on pecans (MRID #434500-01).

CONCLUSIONS

1. Hand-written changes have been made to the Enable 2F label to change "EPA registered spray adjuvant" to "spray adjuvant approved for use with registered crop protection chemicals".

2. The requested revisions to the analytical method have been made except for the following:

Equation 2 on page 15 of the revised analytical method TR No. 34-94-161 should be as follows:

$$\frac{\text{Final Sample Vol. (ml) X Component Conc. (ug/ml)}}{\text{Sample Weight (g)}} = \text{ppm}$$

The equation presented in the submitted method will result in a 100-fold error in the calculated residue level.

RECOMMENDATIONS

CBTS recommends against the proposed tolerance for fenbuconazole on pecans for the reason given in Conclusion #2 above. A revised analytical method must be submitted with Equation 2 as written in Conclusion #2 above. The revised method will be sent to FDA for publication in the Pesticide Analytical Manual (PAM) upon our recommendation for a permanent tolerance.

DETAILED CONSIDERATIONS

Deficiencies from the reviews of PP#1F3995 dated 10/25/94 (N. Dodd, CBTS #13774 and CBTS #14546) are repeated below, followed by the petitioner's responses and CBTS's conclusions.

Deficiency #2 (CBTS #13774)

The petitioner now refers to "EPA-registered" adjuvants. Since EPA does not "register" adjuvants, this terminology is not appropriate and should be removed from the labels. EPA will accept reference to "EPA approved" adjuvants. Revised labels reflecting the appropriate terminology must be submitted.

Petitioner's Response to Deficiency #2

Rohm and Haas Company has "gotten conflicting comments from different Branches of RD at EPA regarding the words "EPA-registered" or "EPA-approved" when describing surfactants to be used with our crop protection products. The label to be used for fenbuconazole (Enable® Fungicide) will use the language recommended in your 01NOV94 letter. A hand-written alteration, which complies with FRB's request for the pages in question, is included with this letter. Because further alteration of the label may be necessary after our conversation with EEB I have not amended the current label at this time. I trust this is satisfactory."

CBTS's Conclusion #2

Deficiency #2 is resolved. Hand-written changes have been made to the Enable 2F label to change "EPA registered spray adjuvant" to "spray adjuvant approved for use with registered crop protection chemicals".

Deficiency #4 (CBTS #13774) and Deficiency from CBTS #14546

A satisfactory EPA method validation for fenbuconazole (RH-7592), RH-9129, and RH-9130 on pecans has been conducted by EPA's Analytical Chemistry Branch. Although satisfactory recoveries were obtained, the method must be revised to include the minor modifications below. The revised method should be submitted so that it can be sent to FDA for publication in the Pesticide Analytical Manual (PAM) upon our recommendation for a permanent tolerance.

EPA's Analytical Chemistry Laboratory safety policy precludes overnight Soxhlet extractions. The petitioner should be asked if the soxhlet extraction can be shortened.

The section on preparation of standard curves states that the response of the analytes "are usually quadratic in nature." If instrument response is not linear, standard and sample response must be carefully matched if a standard curve is not used for quantitation."

Average recovery values are used for calculating residue levels. This practice should not be incorporated in a tolerance enforcement method.

Petitioner's Response to Deficiency #4 (CBTS #13774) and Deficiency from CBTS #14546

A revised method (Rohm and Haas Technical Report No. 34-94-161, revised Nov. 4, 1994, MRID #434500-01) is submitted for inclusion in PAM II. The following revisions have been made:

a. The Soxhlet extraction time has been shortened to 6-8 hours.

b. "A statement on preparation of standard curves that the response of the analytes "are usually quadratic in nature" has been rewritten as "If instrument response is not linear, standard and sample response must be carefully matched if a standard curve is not used for quantitation."

c. Equation 2 on page 13 of TR No. 34-91-14 was as follows:

$$\frac{\text{Final Sample Vol. (ml) X Component Conc. (ug/ml) X 100}}{\text{Average Recovery (\%) X Sample Weight (g)}} = \text{ppm}$$

This has been changed to Eq. 2 on page 15 of the revised method TR No. 34-94-161):

$$\frac{\text{Final Sample Vol. (ml) X Component Conc. (ug/ml) X 100}}{\text{Sample Weight (g)}} = \text{ppm}$$

CBTS's Conclusions re. Deficiency #4 (CBTS #13774) and Deficiency from CBTS #14546

The deficiencies "a" and "b" (above) are resolved by submission of the revised analytical method which incorporates the requested minor revisions.

Regarding "c", Equation 2 on page 15 of the revised analytical method TR No. 34-94-161 should be as follows (ie. with the "X 100" in the numerator deleted since the average recovery expressed as a percent has been deleted from the denominator):

$$\frac{\text{Final Sample Vol. (ml) X Component Conc. (ug/ml)}}{\text{Sample Weight (g)}} = \text{ppm}$$

The equation presented in the submitted method will result in a 100-fold error in the calculated residue level.

cc: RF, SF, Circu., N. Dodd (CBTS), E. Haeberer (CBTS), W. Wassell (CBTS), PP#1F3995, PM #22, Albin Kocialski (CCB), MTO File, M. Bradley (CBTS), D. Marlow (ACB/BEAD), H. Hundley (ACB/BEAD)

RDI:E. Haeberer:12/14/94:M. Flood:12/15/94
7509C:CM#2:Rm804F:305-5681:N. Dodd:nd:12/16/94