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

10/27/94

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#1F03989 (CBTS #'s 13769; Barcode #D203669). Fenbuconazole on Stone Fruit. Amendment dated 5/17/94. (No MRID #).

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 R. Loranger
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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#1F3989 on stone fruit (N. Dodd, 4/12/94 and 4/18/94). This amendment contains a letter dated 5/17/94, a revised Section F for stone fruit, and an amended Section B with revised labels for Indar® 2F and Indar™ 75 WSP on stone fruit, and Confidential Statements of Formulas (CSF's) for fenbuconazole technical dated 5/3/94, Indar® 2F Agricultural Fungicide dated 7/13/93, and Indar™ (RH-7592) 75 WSP Agricultural Fungicide dated 5/18/94. The revised Section F proposes a tolerance for the stone fruit crop group (except plums and prunes) at 2.0 ppm.

CONCLUSIONS

1. CBTS agreed in a phone conversation on 5/3/94 (N.Dodd, 5/5/94) that the company could add a statement on the label which refers to directions on the manufacturers' labels instead of indicating the amount of the surfactant or spray oil (v/v) to be added to the

spray solution on the label. Referring to directions on the manufacturers' labels would be appropriate because each product contains such directions and because Rohm and Haas cannot determine vol/vol without knowing the concentration of each product.

2. 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.

3. A revised Section B/label for Indar 2F has been submitted which indicates that repeat applications should be made on a 7-10 day treatment schedule for apricots, cherries, nectarines, and peaches.

4. Adequate storage stability data have been submitted for fenbuconazole (RH-7592), RH-9129, and RH-9130 on stone fruit for a period of 30 months. Based on average corrected percent recoveries of stored samples, residues in peaches decreased 12.52% for RH-7592, 26.19% for RH-9130, and 20.99% for RH-9129 over the 30-month period.

5. Additional storage stability data for stone fruit reflecting storage intervals up to 49 months should be submitted.

6. Pending submission of the requested storage stability data for stone fruit for a period of 49 months, CBTS tentatively concludes that residues of fenbuconazole (RH-7592), RH-9129, and RH-9130 on the stone fruit crop group (except plums and prunes) will not exceed the proposed tolerance of 2.0 ppm. A final conclusion regarding the adequacy of the proposed tolerance cannot be made until storage stability data reflecting a 49-month storage period are provided.

7. A revised Section B with labels for Indar 2F and Indar 75 WSP has been submitted with the following statement added under "Use Directions for Stonefruits": "For all crops, do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock."

8. The first sentence under "USE DIRECTIONS FOR STONEFRUIT" on the RH-7592 75 WSP label (ie., "Use one 2-ounce pouch of RH-7592 75 WSP per acre in a minimum of 50 gallons spray.") should also state the lb active ingredient per acre.

RECOMMENDATIONS

TOX considerations permitting and provided that a revised Section B is submitted which incorporates the revisions requested in Conclusions #'s 2 and 8 above, CBTS has no objections to a **time-limited tolerance** for fenbuconazole on the stone fruit crop group

(except plums and prunes) at 2.0 ppm. Although deficiencies #5 and #6 are also outstanding, CBTS can use the storage stability data for the 30-month storage interval on an interim basis to support the proposed tolerance for fenbuconazole on the stone fruit crop group (except plums and prunes) until the 49-month storage stability data can be provided.

Registration Division will determine whether the inerts in the formulation Indar® 2F Agricultural Fungicide are cleared under 40 CFR 180.1001.

DETAILED CONSIDERATIONS

Deficiencies from the reviews of PP#1F3989 dated 4/12/94 (N. Dodd) and 4/18/94 (N. Dodd) are repeated below, followed by the petitioner's responses and CBTS's conclusions. (The deficiencies are numbered as in the 4/12/94 and 4/18/94 reviews.)

Deficiency #3 (4/12/94 review) and #3 (4/18/94 review)

The amount of the surfactant or spray oil (v/v) to be added to the spray solution was not added to the label. The petitioner should submit a revised Section B/label which indicates the amount of the surfactant or spray oil (v/v) to be added to the spray solution.

Petitioner's Response to Deficiency #3 (4/12/94 review) and #3 (4/18/94 review)

A revised Section B with revised labels for Indar 2F and Indar 75 WSP for stone fruit has been submitted. The labels are revised in accordance with the agreement reached with EPA in a phone conversation on 5/3/94. The following statement has been added under "General Information" on both the Indar 2F and Indar 75 WSP labels: "A wetting agent such as LATRON B-1956, LATRON CS-7 or other EPA-registered spray adjuvant should be added to spray solutions according to manufacturers' use instructions to achieve optimum disease control." The following statement has been added under "Compatibility" on the Indar 2F label: "Follow the manufacturer's instructions for any registered adjuvant to achieve proper spray concentrations."

CBTS's Conclusion #3 (4/12/94 review) and #3 (4/18/94 review)

Deficiency #3 is resolved by submission of the revised Section B/labels. CBTS agreed in a phone conversation on 5/3/94 (N.Dodd, 5/5/94) that the company could add a statement on the label which refers to directions on the manufacturers' labels instead of indicating the amount of the surfactant or spray oil (v/v) to be added to the spray solution on the label. Referring to directions on the manufacturers' labels would be appropriate because each product contains such directions and because Rohm and Haas cannot

determine vol/vol without knowing the concentration of each product.

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.

Deficiency #4 (4/12/94 review)

The label for Indar 2F should be revised to state the interval between repeat applications for fruit brown rot on apricots, cherries, nectarines, peaches, plums, and prunes.

Petitioner's Response to Deficiency #4 (4/12/94 review)

A revised Section B/label for Indar 2F has been submitted which indicates that repeat applications should be made on a 7-10 day treatment schedule for apricots, cherries, nectarines, and peaches. Plums and prunes have been deleted from the label since they have been deleted from the petition. The revised Section F proposes a tolerance for the stone fruit crop group (except plums and prunes) at 2.0 ppm.

CBTS's Conclusion #4 (4/12/94 review)

Deficiency #4 is resolved by submission of the revised Section B/label.

Deficiency #8 (4/12/94 review) and #7 (4/18/94 review)

Additional storage stability data for stone fruit reflecting storage intervals up to 49 months should be submitted.

Petitioner's Response to Deficiency #8 (4/12/94 review) and #7 (4/18/94 review)

Summary tables 1A, 1B, and 1C containing stone fruit storage stability data are submitted for a period of 30 months. The study will be continued for 54 months.

CBTS's Discussion #8 (4/12/94 review) and #7 (4/18/94 review)

These summary tables (1A, 1B, and 1C) were submitted in MRID #433335-01 (PP#1F3989, N. Dodd, October 1994, CBTS #14199, Barcode #206533). Refer to that review for details.

CBTS's Conclusion #8 (4/12/94 review) and #7 (4/18/94 review)

Adequate storage stability data have been submitted for fenbuconazole (RH-7592), RH-9129, and RH-9130 on stone fruit for a

period of 30 months. Based on average corrected percent recoveries of stored samples, residues in peaches decreased 12.52% for RH-7592, 26.19% for RH-9130, and 20.99% for RH-9129 over the 30-month period.

Additional storage stability data for stone fruit reflecting storage intervals up to 49 months should be submitted.

Deficiency #9 (4/12/94 review) and #8 (4/18/94 review)

CBTS tentatively concludes that the available residue data on the representative commodities peaches, plums, and cherries indicate that residues in stone fruit resulting from the proposed use will not exceed the proposed tolerance of 2 ppm for the stone fruit crop group. However, a final conclusion cannot be made until issues regarding the proposed use and storage stability data are resolved.

Petitioner's Response to Deficiency #9 (4/12/94 review) and #8 (4/18/94 review)

The petitioner has responded to issues regarding proposed use and storage stability.

CBTS's Conclusion #9 (4/12/94 review) and #8 (4/18/94 review)

Pending submission of the requested storage stability data for stone fruit for a period of 49 months, CBTS tentatively concludes that residues of fenbuconazole (RH-7592), RH-9129, and RH-9130 on the stone fruit crop group (except plums and prunes) will not exceed the proposed tolerance of 2.0 ppm. A final conclusion regarding the adequacy of the proposed tolerance cannot be made until storage stability data reflecting a 49-month storage period are provided.

Deficiency #10 (4/12/94 review) and #2 (4/18/94 review)

The statement " Do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock. " should be put back on the label.

Petitioner's Response to Deficiency #10 (4/12/94 review) and #2 (4/18/94 review)

The petitioner has submitted a revised Section B/labels for Indar 2F and Indar 75 WSP with the following statement added under "Use Directions for Stonefruits": "For all crops, do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock."

CBTS's Conclusion #10 (4/12/94 review) and #2 (4/18/94 review)

Deficiency #10 is resolved by submission of the revised Section B/labels.

Deficiency #4 (4/18/94 review)

The first sentence under "USE DIRECTIONS FOR STONEFRUIT" on the RH-7592 75 WSP label (ie., "Use one 2-ounce pouch of RH-7592 75 WSP per acre in a minimum of 50 gallons spray.") should also state the lb active ingredient per acre.

Petitioner's Response to Deficiency #4 (4/18/94 review)

None.

Conclusion #4 (4/18/94 review)

Deficiency #4 (4/18/94 review) remains outstanding. The first sentence under "USE DIRECTIONS FOR STONEFRUIT" on the RH-7592 75 WSP label (ie., "Use one 2-ounce pouch of RH-7592 75 WSP per acre in a minimum of 50 gallons spray.") should also state the lb active ingredient per acre.

cc: RF, Circu., N. Dodd (CBTS), E. Haeberer (CBTS), W. Wassell (CBTS), PP#1F3989, PM #22, Albin Kocialski (CCB)

RDI:E. Haeberer:10/25/ 94:M. Flood:10/25/94
7509C:CM#2:Rm 804F:305-5681:N. Dodd:nd:10/26/94