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

APR 12 1994

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#1F03989 and 4H05689 (CBTS #'s 12884 and 13150; Barcode #'s D197092 and D198819). Fenbuconazole on Stone Fruit. Amendment dated 10/5/93 (No MRID #).

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Tolerance Petition Section II
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Health Effects Division (7509C)

THROUGH: Debra Edwards, Ph.D., Chief Debra Edwards
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TO: Cynthia Giles-Parker, PM #22
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and

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Chemical Coordination Branch
Health Effects Division (7509C)

Rohm and Haas Company has responded to a fenbuconazole review of PP#1F3989 on stone fruit (N. Dodd, 3/10/93). This amendment contains a letter dated 10/5/93, a revised Section F for stone fruit, and an amended Section B/label for stone fruit. The revised Section F proposes a tolerance of 2.0 ppm on the stone fruit crop group and a food additive tolerance of 7.0 ppm on dried prunes.

CONCLUSIONS

1. All Product Chemistry data deficiencies have been resolved (PP#1F3989, CBTS #'s 12265 and 12266, N. Dodd, 4/4/94).

2. CBTS has deferred to Registration Division concerning whether the inerts in the formulation Indar® 2F Agricultural Fungicide are cleared under 40 CFR 180.1001. No CBTS action is needed.

3. 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.

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

5. Reanalysis of the peach fruit from the triazole labelled fenbuconazole metabolism study indicates that RH-4911 is a minor residue in stone fruits. Therefore, the nature of the residue in stone fruits is adequately defined. The residues of concern in stone fruits are parent (RH-7592) and its metabolites RH-9129 and RH-9130.

6. A satisfactory method trial has been conducted by EPA's Analytical Chemistry Laboratory for the method in Rohm and Haas Technical Report No. 34-90-47R (MRID #430444-01) on peaches.

7. Analytical reference standards for RH-7592, RH-9129, RH-9130, and RH-6467 have been sent to EPA's Chemical Standards Repository.

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

9. 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.

10. 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.

RECOMMENDATIONS

CBTS recommends against the proposed tolerance for fenbuconazole on stone fruit for reasons given in Conclusions #'s 3, 4, 8, 9, and 10 above.

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 review of PP#1F3989 dated 3/10/93 (N. Dodd) are repeated below, followed by the petitioner's responses and CBTS's conclusions. (The deficiencies are numbered as in the 3/10/93 review.)

Deficiencies #1 and #2

The Product Chemistry data are not adequate to support the proposed **permanent** tolerances. Additional Product Chemistry data under §61-1, 61-2, 61-3, 62-1, 62-3, 63-7, 63-8, 63-12, and 63-13 are needed. [See "Fenbuconazole (RH-7592) Product Chemistry Data Submitted to Support New Registrations", N. Dodd, February 25, 1993.]

The manufacturing process is not adequately delineated. Additional data under §61-2 (Beginning Materials and Manufacturing Process) and §61-3 (Discussion of Formation of Impurities) are needed to support a **permanent** tolerance. (Refer to the Product Chemistry review, N. Dodd, February 25, 1993.)

Petitioner's Response to Deficiencies #1 and #2

Rohm and Haas has responded to the product chemistry data deficiencies cited in the 2/25/93 review.

CBTS's Conclusions #1 and #2

All Product Chemistry data deficiencies have been resolved (PP#1F3989, CBTS #'s 12265 and 12266, N. Dodd, 4/4/94).

Deficiency #3

CBTS defers to Registration Division concerning whether the inerts in the formulation Indar® 2F Agricultural Fungicide are cleared under 40 CFR 180.1001.

CBTS's Conclusion #3

Registration Division determines whether inerts are cleared under 40 CFR 180.1001. No CBTS action is needed.

Deficiency #4a

Since no residue data reflecting postharvest treatments have been provided, the label should be revised to delete the statement "Additional applications may be made after harvest" which appears regarding leaf spot on cherries. Alternatively, postharvest residue data should be submitted.

Petitioner's Response to Deficiency #4a

"In the case of fenbuconazole, 'post-harvest use' refers to the cherry trees, not the fruit, that is, the tree after all the fruit has been harvested. This use is to prevent the defoliation of the trees which occurs if they are infected with the cherry leaf spot disease (Blumeriella sp.). The defoliation compromises the ability of the tree to produce fruit in the following year. No fruit receives treatment during this use."

The revised label dated 9/30/93 contains the following statement under use directions for cherries: "Additional foliar applications may be made after harvest."

CBTS's Conclusion #4a

Deficiency #4a is resolved by the clarification and revised label.

Deficiency #4b

The label should be revised to state the maximum number of applications/year.

Petitioner's Response to Deficiency #4b

A revised Section B/label dated 9/30/93 has been submitted. The following statements have been added to the "USE DIRECTIONS FOR STONEFRUITS":

"For all crops, except peaches, do not make more than six applications or apply more than 1.5 quarts (0.75 lbs active) per season."

"For peaches, do not make more than eight applications or apply more than 2.0 quarts (1.0 lb active) per acre per season."

CBTS's Conclusion #4b

Deficiency #4b has been resolved by submission of the revised label.

Deficiency #4c

The label should be revised to indicate the names and quantities (v/v) of wetting agents/surfactants or emulsifiable spray oils to be added to the spray solution. (The petitioner must be reminded that representative residue data reflecting use of the wetting agents/surfactants and emulsifiable spray oils should be available. In cases where such data are not available, reference to the wetting agents/surfactants or emulsifiable spray oils should be deleted from the label.)

Petitioner's Response to Deficiency #4c

"The EPA initially requested that Rohm and Haas specify which adjuvants were acceptable. The language proposed to EPA to address this concern was accepted by them in phone conversations. This language has been added to the label as General Information."

"The EPA also inquired how the residue trials were conducted. The trials were nearly all conducted with a spray adjuvant. Since this practice creates a maximum likelihood for crop residues, EPA accepted the data submitted as adequate support for the proposed tolerances."

CBTS's Discussion #4c

This issue was discussed by phone in connection with the petition on stone fruits (PP#1F3989, N. Dodd, 5/26/93). CBTS determined that a term such as "nonionic surfactant" is specific enough. EPA also had no objection to the statement "Use of a surfactant improves performance but is not a required additive".

Under "General Information", the previous label stated "A wetting agent or emulsifiable spray oil should be added to spray solutions to achieve optimum disease control". The revised label (under "General Information") states " A wetting agent such as LATRON B-1956 OR LATRON CS-7 spray adjuvant should be added to spray solutions to achieve optimum disease control." Under "USE DIRECTIONS FOR STONEFRUITS", both the old and revised labels recommend use of an "agricultural spray adjuvant". (To summarize: Instead of the terms "wetting agent or emulsifiable spray oil" which were on the previous label, the revised label names "LATRON B-1956 OR LATRON CS-7 spray adjuvant" under "GENERAL INFORMATION" and refers to "an agricultural spray adjuvant" under "USE DIRECTIONS FOR STONEFRUITS".)

The term "agricultural spray adjuvant" under "USE DIRECTIONS FOR STONEFRUITS" in the revised label are nonspecific. However, two examples (Latron B-1956 or Latron CS-7) are given under "GENERAL INFORMATION".

Concerning the availability of representative residue data reflecting use of the wetting agents/surfactants and emulsifiable spray oils, CBTS indicated by phone (PP#1F3989, N. Dodd, 5/26/93) that a statement that most of the residue studies were conducted with a nonionic surfactant would probably be accepted.

CBTS's Conclusion #4c

Deficiency #4c is not resolved because 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.

Deficiencies #4d and #10b

The label 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 Deficiencies #4d and #10b

A revised Section B/label has been submitted.

CBTS's Discussion #4d and #10b

No change was made concerning the timing of applications for fruit brown rot. Under apricots, both the old and revised labels say "Begin applications 3 weeks before harvest". If subsequent applications are to occur at full bloom and at petal-fall (as for blossom blight), this should be indicated in some way. Otherwise, the intervals between applications should be stated.

CBTS's Conclusions #4d and #10b

Deficiencies #4d and #10b remain outstanding. The label should be revised to state the interval between repeat applications for fruit brown rot on apricots, cherries, nectarines, peaches, plums, and prunes.

Deficiency #4e

The label should be revised for full coverage sprays so that the dosage is expressed as pounds active ingredient per 100 gallons spray solution to run-off. For concentrated sprays, the amount of active ingredient per acre should be stated and should be the same or less active ingredient per acre as the amount which would be applied using a full coverage spray. The label should contain the following additional instructions:

> In order to apply the correct amount of pesticide to your orchard, you must know the number of gallons of water needed to spray one acre of your trees to the point of drip. If you do not already know this gallonage, you should conduct a test to determine it. For a dilute spray, this volume (containing "x" lbs./100 gals) should be used to treat the orchard. For a concentrate spray, the amount of pesticide required to treat the orchard is the same or less as that contained in the above gallonage of dilute spray. For a concentrate spray, the recommended gallonage is "y" gallons/A.

Petitioner's Response to Deficiency #4e

The following directions have been added for ground applications:

Ground- "Thorough coverage sprays generally result in optimum disease control. To achieve good coverage use proper spray pressure, gallonage per acre, nozzles, nozzle spacing and tractor speed. Consult spray nozzle and accessory catalogues for specific information on proper equipment calibration. For tree fruits and nuts, the same amount of RH-7592 2F fungicide should be applied per acre in either dilute or concentrate sprays."

Dilute Sprays:

"To apply the correct amount of RH-7592 2F fungicide to your orchard, you must know the number of gallons of water needed to spray one acre of trees to the point of drip. If you do not already know this gallonage, you should conduct a test to determine it. For a dilute spray, this volume (containing 2 fluid ounces or 0.03 pounds active RH-7592 2F fungicide per 100 gallons) should be used to treat the orchard."

Concentrate Sprays:

"The amount of RH-7592 2F fungicide required to treat the orchard is the same as that contained in the above gallonage for dilute sprays. For a concentrate spray, a minimum of 50 gallons per acre is recommended."

CBTS's Conclusion #4e

Deficiency #4e is resolved by submission of the revised Section B/label with the requested instructions.

Deficiencies #5a and #5b

The registrant must provide the chemical name for RH-7592 according to CAS nomenclature (or another well-defined nomenclature) on the Section B/label and Section F if this has not been done. To verify that the name for the active ingredient on the Section B/label and Section F is a Chemical Abstracts Service (CAS) name (or another well-defined name from another source), the petitioner should submit to EPA a copy of the appropriate memoranda from CAS (or another source) which identifies the CAS name (or other well-defined name).

The names for the metabolites of concern should correspond to the appropriate name for RH-7592.

Petitioner's Response to Deficiencies #5a and #5b

The petitioner has submitted revised Sections B and F.

CBTS's Discussion re. Deficiencies #5a and #5b

CAS nomenclature for fenbuconazole and its metabolites RH-9129, RH-9130, and RH-6467 have been submitted (PP#1F3989/PP#1F3995, N. Dodd, 9/29/93).

The revised Section B/label contains the CAS name for fenbuconazole.

The revised Section F contains the CAS nomenclature for fenbuconazole, RH-9129, and RH-9130.

CBTS's Conclusions #5a and #5b

Deficiencies #5a and #5b are resolved by submission of the revised Sections B and F containing CAS nomenclature for fenbuconazole and its metabolites.

Deficiency #6

The major residues in stone fruit are fenbuconazole (RH-7592), RH-9129 and its isomer RH-9130, triazolealanine, and triazoleacetic acid. The decision as to which metabolites should be included in the tolerance expression will be deferred to the HED Metabolism Committee.

Note: The HED Metabolism Committee determined on 3/1/94 that the residues of concern on stone fruit, pecans, wheat, bananas, apples, and almonds are parent (RH-7592) and the metabolites RH-9129 and RH-9130, provided that the petitioner shows that RH-4911 is only a minor residue in these crops (PP#1F3989, N. Dodd and W. Wassell, 3/16/94). In connection with the petition on pecans, data concerning the conjugated metabolite RH-4911 in the metabolism studies (ie. from peanut vines, peach fruit, and wheat straw) and in residue field trials on pecans were reviewed (PP#1F3995, CBTS #13342, N. Dodd, 4/5/94). No residue data for RH-4911 in stone fruits were submitted. However, glucose conjugates of RH-4911 accounted for only 4.4% of the total radioactive residue (0.006 ppm) in peach fruit from the triazole labelled fenbuconazole metabolism study.

Petitioner's Response to Deficiency #6b

The petitioner provided data concerning the conjugated metabolite RH-4911 in the metabolism studies (ie. from peanut vines, peach fruit, and wheat straw).

CBTS's Conclusion #6b

Deficiency #6b is resolved. Reanalysis of the peach fruit from the triazole labelled fenbuconazole metabolism study indicates that RH-4911 is a minor residue in stone fruits. Therefore, the nature of the residue in stone fruits is adequately defined. The residues of concern in stone fruits are parent (RH-7592) and its metabolites RH-9129 and RH-9130.

Deficiency #7a

An EPA method validation is needed for the analytical method for stone fruits which is described in Rohm and Haas Technical Report #34-90-47 (MRID #418750-38) for parent, RH-9129, and RH-9130.

Note: An EPA method validation was conducted for the analytical method for stone fruits which is described in Rohm and Haas Technical Report #34-90-47 (MRID #418750-38) for parent, RH-9129, and RH-9130. EPA concluded (PP#1F03989, N. Dodd, 10/25/93) that the method should be revised to include four minor modifications.

Petitioner's Response to Deficiency #7a

Rohm and Haas submitted a revised analytical method in Rohm and Haas Technical Report No. 34-90-47R (MRID #430444-01).

CBTS's Conclusion #7a

Deficiency #7a is resolved. CBTS concluded (PP#1F03989, CBTS #13001, N. Dodd, April 1994) that a satisfactory method trial has been conducted by EPA's Analytical Chemistry Laboratory for the method in Rohm and Haas Technical Report No. 34-90-47R (MRID #430444-01) on peaches.

Deficiency #7b

The petitioner should send analytical reference standards and individual Material Safety Data Sheets (as required by OSHA in 29 CFR 1910.1200) for RH-9129 and RH-9130 to the following address:

Pesticide and Industrial Chemical Repository (MD-8)
U.S. Environmental Protection Agency
Research Triangle Park, N.C. 27711

Petitioner's Response to Deficiency #7b

The petitioner has submitted a letter dated 1/12/94 from Seymour Gold of the U.S. EPA's Chemical Standards Repository to Dr. Richard Costlow of Rohm and Haas. This letter acknowledges receipt of analytical reference standards for fenbuconazole technical (707-

EGN), fenbuconazole 2F (707-EGR), and the fenbuconazole metabolites RH-9129, RH-9130, and RH-6467.

CBTS's Conclusion #7b

Deficiency #7b is resolved. Analytical reference standards for RH-7592, RH-9129, RH-9130, and RH-6467 have been sent to EPA's Chemical Standards Repository.

Deficiency #9

Additional storage stability data on stone fruit are needed to support permanent tolerances for the following reasons:

Since the 0 day analyses in MRID #'s 418750-37 (cherries, plums, and peaches) and 418750-36 (almonds) were performed by Craven Laboratories, the storage stability studies in MRID #'s 418750-37 and 418750-36 will not be used to support a regulatory decision.

No conclusion regarding the storage stability of parent and its metabolites of concern (RH-9129 and RH-9130) can be drawn from the study in MRID #418750-42 (cherries, plums, and peaches) since initial levels of metabolites are not reported. These data compare residues of parent (1988) to residues of parent and the metabolites RH-9129 and RH-9130 (1991).

Petitioner's Response to Deficiency #9

The requested data have been submitted.

CBTS's Discussion re. Deficiency #9

CBTS concluded (PP#1F03989, CBTS #'s 12565 and 12566, N. Dodd, 2/24/94) that residues of fenbuconazole and its metabolites RH-9129 and RH-9130 are stable during frozen storage at approximately -10°C for up to approximately 18 months in or on peaches. However, since some of the residue data were analyzed or reanalyzed at much longer PHI's, additional storage stability data for stone fruit reflecting storage intervals up to 49 months were requested.

CBTS's Conclusion #9

Deficiency #9 remains outstanding. Additional storage stability data for stone fruit reflecting storage intervals up to 49 months should be submitted.

Deficiency #10a

No residue data reflecting postharvest treatments have been provided. Therefore, the statement "Additional applications may be made after harvest" which appears regarding leaf spot on cherries

should be deleted. Alternatively, postharvest residue data should be submitted.

Petitioner's Response to Deficiency #10a

As explained in #4a above, the applications to be made after harvest are to cherry trees to be treated after the fruit has been removed. No fruit receives postharvest treatment. The revised label dated 9/30/93 clarifies the use by referring to foliar applications.

CBTS's Conclusion #10a

Deficiency #10 is resolved by the explanation and revised label.

Deficiency #10c

The proposed use indicates that a wetting agent or emulsifiable spray oil should be added to the spray solutions. However, only one residue study (MRID #418750-41; peaches in GA, Triton B1956, 0.06% v/v) indicated that a wetting agent or spray oil was added. The petitioner should indicate whether wetting agents and emulsifiable spray oils were added in other studies.

Petitioner's Response to Deficiency #10c

As discussed in #4c above, the petitioner has indicated that the trials were nearly all conducted with a spray adjuvant.

CBTS's Discussion re. Deficiency #10c

CBTS expects higher residues to result with use of a spray adjuvant than would occur without one.

CBTS's Conclusion #10c

Deficiency #10c is resolved by the petitioner's statement that most of the trials were conducted with a spray adjuvant.

Deficiency #10d

CBTS tentatively concludes that the available residue data on peaches, plums, and cherries indicate that residues in peaches, plums, and cherries 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, analytical method, and storage stability data are resolved.

Petitioner's Response to Deficiency #10d

The petitioner indicates that the requested data have been submitted.

CBTS's Discussion #10d

The issues regarding the analytical method have been resolved. However, some issues regarding the proposed use and storage stability have not been resolved.

CBTS's Conclusion #10d

Deficiency #10d remains outstanding. 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.

Deficiency #10e

A revised Section F should be submitted in which a food additive tolerance on dried prunes of 7 ppm is proposed. The food additive tolerance on dried prunes should be about 3.4X the proposed tolerance on the stone fruit crop group.

Petitioner's Response to Deficiency #10e

The petitioner has submitted a revised Section F which proposes a tolerance for fenbuconazole, RH-9129, and RH-9130 of 2.0 ppm on the stone fruit crop group and 7.0 ppm on dried prunes.

CBTS's Conclusion #10e

Deficiency #10e is resolved by submission of the revised Section F.

Other

Several other changes have been made to the label as described below:

The previous label allowed application by ground equipment. The revised label allows both ground and aerial applications. Aerial applications are to be made in a minimum of 5 gallons water per acre on annual crops and 10 gallons water per acre on perennial tree fruits and nuts.

For scab on peaches, the previous label said "Begin applications 7-10 days after shuck split." The revised label says "Begin applications at shuck split."

The previous label said " Do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock." This was left off the revised label.

Conclusion re. Label Changes

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.

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

RDI:E. Haeberer:4/11/94:R. Loranger:4/11/94
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