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

MAR 9 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: **PP#6F3454**. Bifenthrin in/on Pears, Pecans, Walnuts, and Strawberries. Amendment in Response to Review of 1/10/91. CBTS# 10,817. DP Barcode D184317. MRID#'s 425334-00, 425334-01, 425156-01, 425156-02, 425156-03, 425571-01, 423571-02, and 418946-01.

FROM: José J. Morales, Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
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José J. Morales 3/9/94

THROUGH: Debra Edwards, Ph.D., Chief
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BACKGROUND

FMC Corporation submits an amendment to PP#6F3454, which requested the establishment of tolerances for the insecticide/miticide bifenthrin [(2-methyl[1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate] in/on pears, strawberries, walnuts, and pecans. The amendment consists of a letter dated 10/27/92, additional residue data, revised Section B, storage stability data, and a revised Section F.

FMC now requests establishment of tolerances for bifenthrin on pears at 1.0 ppm, strawberries at 3.0 ppm, walnuts at 0.05 ppm, and pecans at 0.05 ppm.

SUMMARY OF DEFICIENCIES THAT NEED TO BE RESOLVED

1. A revised Section B for Pecans needs to be submitted.

2. Successful EPA validation of analytical method.

CONCLUSIONS AND RECOMMENDATIONS

1. The petitioner submitted a clean copy of the analytical method for walnuts and pecans. The Agency will request a method validation.

2. Reports of multiresidue testing for bifenthrin and 4'-hydroxy bifenthrin through FDA protocols A through E have been forwarded to FDA for review. Bifenthrin and 4'-hydroxy bifenthrin could be recovered under protocols D or E, depending on the matrix.

3. The petitioner submitted a revised Section B for pears in which the suggestions made by CBTS are incorporated.

4. Adequate storage stability data have been submitted for bifenthrin in various crops for periods up to 49 months.

5. The submitted residue data for strawberries reflect applications in a minimum of 50 gallons of finished spray per acre for ground applications, a minimum of 10 gallons of finished spray per acre for aerial applications, and at intervals of at least 6 days between applications. Residues of bifenthrin in the treated fruit ranged from 0.07 ppm to 0.86 ppm. The maximum residue observed in previously submitted data was 2.3 ppm. CBTS concludes that the proposed tolerance of 3 ppm for residues of bifenthrin in/on strawberries is adequate and supported by the submitted residue data.

6. The submitted residue data for walnuts reflect applications in a minimum of 115 gallons of finished spray per acre for ground applications and 20 gallons of finished spray per acre for aerial applications and at intervals of at least 23 days between applications. Residues of bifenthrin in treated walnuts were non-detectable. The petitioner submitted a revised Section B for walnuts proposing a 25 day spray interval for Brigade® 10WP. CBTS concludes that the proposed tolerance of 0.05 ppm in/on walnuts and the 25 day spray interval are adequate and supported by the submitted residue data.

7. Although the petitioner states that the label for pecans has been revised to recommend applications in 300 gallons of finished spray, the only change observed is the addition of a 15 day spray interval. No change was made to

the minimum spray volumes. Also, the old label for pecans specified a PHI of 21 days and this PHI is not specified in the new submitted label. A 21 day PHI should be added to the proposed label for pecans. A revised Section B is needed.

CBTS recommends against the proposed tolerance for reasons given in Conclusion 7.

DETAILED CONSIDERATIONS

The deficiencies listed in CBTS memo of 1/10/91 (PP#6F3454, N. Dodd, 1/10/91) are outlined below followed by the petitioner's responses and CBTS comments

CBTS Deficiency #6a(2)

An adequate method validation for pecans and walnuts has been conducted by an independent laboratory on a modified version of Method I. Since significant modifications were made to the method for nuts, a clean copy of the complete method (with all details and with significant modifications included, and with old directions deleted) should be submitted so that it can be sent to EPA's laboratory for validation without further explanation.

Petitioner's Response to Deficiency #6a(2)

The petitioner submitted a clean copy of the complete method that includes the modifications referred to by the Agency.

CBTS Comments

The petitioner submitted a clean copy of the analytical method for walnuts and pecans. The Agency will request a method validation.

Deficiency #6a(2) is resolved.

CBTS Deficiency #6b

The petitioner should submit multiresidue data required by Protocol C concerning GC characteristics. The petitioner should also test bifenthrin through Protocol D (formerly Protocol III).

Petitioner's Response to Deficiency #6b

The petitioner stated that the data requested is in the Agency files and is contained in MRID# 423571-01.

CBTS Comments

This deficiency was resolved in PP#7F3546 and discussed in M. Flood's memo of 2/1/93. The following reports were submitted by the petitioner:

"Testing of Bifenthrin through FDA Multi-Residue Protocols A through E"; J. Fomenko; 10/11/91; Spectralytix, Inc., Gaithersburg, MD; FMC Report PC-0164. (MRID# 423571-01)

"Testing of 4'-Hydroxy Bifenthrin through FDA Multi-Residue Protocols A through E"; J. Fomenko, 10/11/91; Spectralytix, Inc., Gaithersburg, MD; FMC Report PC-0165. (MRID# 423686-01)

These volumes were forwarded to FDA for review. Assuming FDA acceptance, this deficiency is resolved. Also, the HED Metabolism Committee has determined that the 4'-hydroxy metabolite need not appear in the tolerance expression.

CBTS Deficiency #9a

Additional residue data on pears may be needed as discussed below.

Petitioner's Response to Deficiency #9a

The petitioner has chosen to modify the proposed label to accommodate the data that has already been submitted to and reviewed by the Agency.

CBTS Comments

See deficiencies 9b, 9c, 9d, 9e, and 9f.

CBTS Deficiency #9b

Since most of the residue data on pears reflect applications in 400 gals. spray/A, the label for pears should be revised to specify application in a spray volume of 400 gals./A or residue data reflecting application in the proposed

spray volume of 200 gals. spray/A should be submitted. Residue data for walnuts and pecans cannot be translated to pears.

Petitioner's Response to Deficiency #9b

The label has been revised to reflect applications in 400 gals. spray/A.

CBTS Comments

The submitted draft label specify application of Brigade® 10WP in a minimum of 400 gals. spray/A.

Deficiency #9b is resolved.

CBTS Deficiency #9c

All residue data on pears reflect ground applications. The petitioner removed the direction for aerial applications from the label. However, a revised Section B/label should be submitted in which the restriction such as "Apply by ground equipment only" is added.

Petitioner's Response to Deficiency #9c

The petitioner explained that since CBTS policy concerning aerial residue data has changed, the label has been revised to include aerial application with the specification that aerial applications are to be made in a minimum of 10 gallons of water per acre.

CBTS Comments

Deficiency #9c is resolved.

CBTS Deficiency #9d

The proposed 15-day interval between applications for pears is not sufficiently represented by residue data. Based on available residue data, a 30-day minimum interval between applications should be proposed for pears in a revised Section B/label, or residue data reflecting a 15-day interval between applications should be submitted.

Petitioner's Response to Deficiency #9d

The label has been revised to include 30 day minimum spray interval.

CBTS Comments

The submitted draft label for Brigade® 10 WP specify a 30-day spray interval between applications.

Deficiency #9d is resolved.

CBTS Deficiency #9e

Since spray oil may be used, residue data reflecting use of spray oil should be submitted or reference to spray oil should be deleted from the label for pears.

Petitioner's Response to Deficiency #9e

Reference to the use of spray oil has been deleted from the label.

CBTS Comments

Deficiency #9e is resolved.

CBTS Deficiency #9f

Residue data on pears reflected samples which were stored up to 28 months. Storage stability data previously reviewed (PP#6F3454, N. Dodd, 7/27/87) were for periods up to 24 months. The petitioner indicates that FMC Report P-2132, dated 4/24/89, contains storage stability data for various crops up to 48 months. This recent data should be submitted with the next amendment to this petition or referenced by MRID#.

Petitioner's Response to Deficiency #9f

A laboratory-spiked cold storage stability study was implemented to determine the effects of cold storage on bifenthrin. The matrices used for the study were lettuce, potato, pecan, cow fat, cow liver, cow milk, cow muscle, and poultry egg. After 36 months of frozen storage, levels of bifenthrin varied by no greater than 16% from the initial spiking level in all matrices. Based on the data collected, bifenthrin can be considered stable on the crop and animal

matrices analyzed for this study for at least 36 months of frozen storage. The reports that contain the storage stability data were submitted to the Agency and assigned MRID#'s 418946-01 and 423571-02.

CBTS Comments

Storage stability data contained in MRID# 423571-02 were submitted with PP# 7F3546 and reviewed in M. Flood's memo of 2/1/93. Samples of lettuce, pecans, potatoes, cow milk and tissue (fat, liver, and muscle), and poultry eggs were fortified with bifenthrin at 0.50 ppm and stored frozen at -18°C for 0, 6, 12, 24, and 36 months prior to analysis. The submitted data indicate that bifenthrin is stable under frozen storage conditions for 36 months.

Storage stability data were submitted in MRID# 418946-01 for apple, corn silage, corn stover, corn grain, cottonseed, sandy loam soil, sandy clay loam soil, silt loam soil. The crops were fortified with bifenthrin at a single level between 0.5 ppm and 1.0 ppm, stored frozen at -18°C for 0, 3, 6, 12, 24, and 49 months prior to analysis. Corn grain samples were analyzed after 9 and 34 months. The submitted data indicate that bifenthrin is stable in apple, corn silage and corn stover under frozen storage conditions for 49 months, in cottonseed for 24 months, and in corn grain for 34 months.

CBTS conclude that adequate storage stability data has been submitted for bifenthrin in various crops for periods up to 49 months. Deficiency #9f is resolved.

CBTS Deficiency #10a

No studies on strawberries approximately represent both the proposed minimum spray volume of 50 gals./A and the proposed minimum spray interval of 7 days. Few studies represent both the minimum spray volume of 50 gals./A and 14-day spray intervals (see 10b and 10d below). To support a permanent tolerance, additional residue data on strawberries should be submitted to reflect a 7-day interval and application in 50 gals. spray per acre. Residue data on strawberries reflecting the proposed use should be made available from the states of CA, FL, OR/WA, IN/MI, NY/OH, and LA. Several representative samples should be analyzed from each study.

Based on the residue data now available and the CBTS policy of using integers rather than fractions for tolerances above 1 ppm, a revised Section F will be needed which proposed an integer tolerance (such as 3 ppm) for strawberries instead of the proposed 2.5 ppm tolerances.

Petitioner's Response to Deficiency #10a

Additional residue data were submitted. The data represent a residue program in which Brigade WSB was applied to strawberries as a broadcast foliar spray. Ground applications were made in 3 trials (OR, NY, LA) and aerial applications were made in 2 trials (CA). Four applications were made with 6 to 16 day intervals between applications. Two of the ground applications were made with spray volumes of 50 and 56 gallons per acre. The two aerial trials were made with spray volumes of 10 gallons per acre. All trials included 0, 1, and 3 day pre-harvest intervals. Residues found in collected fruit samples ranged from 0.07 ppm to 0.86 ppm. The petitioner concludes that the data support the label as proposed in May 18, 1990 and that no label revisions are needed. Concerning the tolerance, although the petitioner disagree with the Agency's policy regarding the use of integers for tolerances above 1.0 ppm, a revised Section F is being submitted to the Agency at this time. In it, the proposed tolerance for strawberries is amended to 3 ppm. A tolerance of 3 ppm is 0.7 ppm greater than the highest residue level analyzed for bifenthrin on strawberries. As a consequence, the calculated estimated dietary exposure to bifenthrin from consuming strawberries would be exaggerated based on a tolerance of 3 ppm. FMC requests a copy of this Agency policy.

CBTS Comments

Residue data reflecting the application of bifenthrin to strawberries appear in the following report:

> "Magnitude of the Residue of Bifenthrin in/on Strawberries Treated with Brigade® WSB"; In-Young Kim; 8/91; Study Number 182STR90R1. Performing laboratory was FMC Corporation, Agricultural Chemical Group, Princeton, NJ (MRID# 425156-02).

Five trials were conducted during 1990 in NY (1), OR (1), LA (1), and CA (2). Among the five trials, ground applications were made in 3 trials (OR, NY, LA) and aerial applications were made in 2 trials (CA). Four applications were made with 6 to 16 day intervals between applications and the rate of each application was 0.2 lbs. ai/A. Control and treated strawberry samples were collected 0, 1, and 3 days after the last application. After pesticide application, samples were shipped frozen to the Residue Chemistry Department, FMC Corporation, Princeton, NJ for residue analysis. In the Residue Chemistry Department, the samples were stored frozen at -18°C until analysis. Strawberry samples were analyzed for bifenthrin residues up to almost 10 months after sampling. Maximum interval between extraction and analysis was not speci. ed. The analytical method was "Determination of FMC 54800 Residues

in/on Strawberries", FMC Corporation, ACG, Princeton, NJ, PC-1073, 2/15/85, with minor modifications. The sensitivity of the method is 0.05 ppm. Control and recoveries were analyzed along with the strawberry samples. Control values were <0.01 ppm. Recoveries at fortification levels of 0.05 ppm and 0.50 ppm ranged from 85% to 112% and 75% to 91% respectively. The analytical method was validated by an independent laboratory in FMC Report PC-0128. Residues of bifenthrin were reported as follows:

Table I. Bifenthrin Residues in/on Strawberries

Trial Location	Application Rate (lbs. ai/A)	Interval (days)	Spray Volume (gals./A)	PHI (days)	Bifenthrin Residue (ppm)
OR					
	control	--	--	--	ND
	4 x 0.2	8	100	0	0.34, 0.46
	4 x 0.2	8	100	1	0.24, 0.34
	4 x 0.2	8	100	3	0.29, 0.30
NY					
	control	--	--	--	ND
	4 x 0.2	7 - 13	50	0	0.24, 0.26
	4 x 0.2	7 - 13	50	1	0.22, 0.23
	4 x 0.2	7 - 13	50	3	0.12, 0.31
LA					
	control	--	--	--	ND
	4 x 0.2	7	56	0	0.75, 0.86
	4 x 0.2	7	56	1	0.75, 0.76
	4 x 0.2	7	56	3	0.58, 0.65
CA[1]					
	control	--	--	--	ND
	4 x 0.2	6 - 16	10	0	0.15, 0.27

Trial Location	Application Rate (lbs. ai/A)	Interval (days)	Spray Volume (gals./A)	PHI (days)	Bifenthrin Residue (ppm)
	4 x 0.2	6 - 16	10	1	0.13, 0.14
	4 x 0.2	6 - 16	10	3	0.16, 0.22
CA[1]					
	control	--	--	--	ND
	4 x 0.2	13 - 16	10	0	0.24, 0.30
	4 x 0.2	13 - 16	10	1	0.09, 0.26
	4 x 0.2	13 - 16	10	3	0.07, 0.15

1 - Aerial applications were made in these trials.

The submitted residue data reflect applications in a minimum of 50 gallons of finished spray per acre for ground applications, a minimum of 10 gallons of finished spray per acre for aerial applications, and at intervals of at least 6 days between applications. Residues of bifenthrin in the treated fruit ranged from 0.07 ppm to 0.86 ppm. The maximum residue observed in previously submitted data was 2.3 ppm. CBTS concludes that the proposed tolerance of 3 ppm for residues of bifenthrin in/on strawberries is adequate and supported by the submitted residue data.

Regarding the Agency's policy of using integers rather than fractions for tolerances above 1 ppm, the petitioner should be aware that this an unwritten working policy within the Branch. Although tolerance levels are used in risk assessment calculations, if the risk calculated from tolerances is too high, anticipated residues will be used to calculate a more accurate dietary burden from consumption.

Deficiency #10a is resolved.

CBTS Deficiency #10b

The revised labels for strawberries indicate that ground applications should be made in a minimum of 50 gals. spray/A. Available residue data reflect ground applications in spray volumes of 26 to 250 gals./A. Few studies approximately represent the minimum spray volume for ground applications.

Petitioner's Response to Deficiency #10b

Additional residue data are being submitted to the Agency. They include two trials in which bifenthrin was applied by ground in 50 and 56 gallons of water per acre. The residues support the proposed tolerance.

CBTS Comments

See deficiency #10a.

Deficiency #10b is resolved.

CBTS Deficiency #10c

Since only one study on strawberries reflects aerial application, additional residue data reflecting aerial applications with the maximum proposed use are needed or the label for strawberries should restrict applications to ground applications.

Petitioner's Response to Deficiency #10c

Residue data from two additional aerial trials were developed using a spray volume of 10 gallons of water per acre. Strawberry samples were collected at 0, 1, and 3 days after the last application. Residues in the samples ranged from 0.07 ppm to 0.86 ppm. The petitioner stated that since the Agency's policy requiring aerial residue data has changed, the aerial data submitted with this response is supplementary information and supports further the proposed label and tolerance.

CBTS Comments

See deficiency #10a.

Deficiency #10c is resolved.

CBTS Deficiency #11a

The revised label for walnuts proposes applications in minimums of 100 gals. spray/A (for concentrate sprays), 200 gals. spray/A (for dilute sprays), or 20 gals. spray/A (for aerial applications). However, five of the eight ground studies reflect application in 400 gals. spray/A. Therefore additional residue data are needed representing the minimum spray volumes and the proposed 15-

day minimum interval between applications. (See 11c). Residue data reflecting the proposed use should be made available from CA and OR. For each additional study which may be conducted, several representative samples from each study should be analyzed.

Petitioner's Response to Deficiency #11a

Residue data from two additional trials were developed. These represent an aerial trial (spray volume - 20 gallons/A) and a ground trial (spray volume - 115 gallons/A). The spray intervals range from 28 to 44 days for the former trial and 23 to 63 days for the latter trial. The residue data for walnuts support the proposed volumes and a 25 day spray interval. A revised label is being submitted in an amended Section B proposing a 25 day spray interval between applications.

CBTS Comments

Residue data reflecting the application of bifenthrin to walnuts appear in the following report:

> "Magnitude of the Residue of Bifenthrin in/on Walnuts Treated with Brigade® WSB"; In-Young Kim; 8/91; Study Number 182WAL90R1. Performing laboratory was FMC Corporation, Agricultural Chemical Group, Princeton, NJ (MRID# 425156-03).

Two trials were conducted during 1990 in California. Ground foliar application was made in one trial and aerial foliar application was made in the other trial. Four applications were made with 23 to 63 day intervals between applications and the rate of each application was 0.2 lbs. ai/A. Control and treated walnut samples were collected 7 days after the last application. After pesticide application, samples were shipped frozen to the Residue Chemistry Department, FMC Corporation, Princeton, NJ for residue analysis. In the Residue Chemistry Department, the samples were stored frozen at -18°C until analysis. Walnut samples were analyzed for bifenthrin residues up to almost 5 months after sampling. Maximum interval between extraction and analysis was 1 day. The analytical method was "Determination of Bifenthrin Residues in/on Pecans", FMC Corporation, ACG, Princeton, NJ, P-1109, 10/3/85, with minor modifications. The sensitivity of the method is 0.05 ppm. The detectability of the method is 0.01 ppm. Control and recoveries were analyzed along with the walnut samples. Control values were <0.01 ppm. Recoveries at a fortification level of 0.05 ppm ranged from 65% to 99%. The analytical method was validated by an independent laboratory in FMC Report PC-0130. Residues of bifenthrin were reported as follows:

Table II. Bifenthrin Residues in/on Walnuts

Trial Location	Application Rate (lbs. ai/A)	Interval (days)	Spray Volume (gals./A)	PHI (days)	Bifenthrin Residue (ppm)
OR[1]					
	control	--	--	--	ND
	4 x 0.2	28 - 31	20	7	ND
	4 x 0.2	28 - 31	20	7	ND
OR[2]					
	control	--	--	--	ND
	4 x 0.2	23 - 63	115	7	ND
	4 x 0.2	23 - 63	115	7	ND

1 - Aerial applications were made in this trial.
2 - Ground applications were made in this trial.

The submitted residue data reflect applications in a minimum of 115 gallons of finished spray per acre for ground applications and 20 gallons of finished spray per acre for aerial applications and at intervals of at least 23 days between applications. Residues of bifenthrin in treated walnuts were non-detectable. The petitioner submitted a revised Section B for walnuts proposing a 25 day spray interval for Brigade® 10WP. CBTS concludes that the proposed tolerance of 0.05 ppm in/on walnuts and the 25 day spray interval are adequate and supported by the submitted residue data.

Deficiency #11a is resolved.

CBTS Deficiency #11c

For walnuts, the proposed minimum interval between applications is 15 days. This spray interval is not well represented in the residue data, which reflect spray intervals to 14 to 97 days. Additional data are needed reflecting the proposed 15-day interval.

Petitioner's Response to Deficiency #11c

Additional data were submitted in support of a 25 day spray interval. A revised label is being submitted in the amended Section B.

CBTS Comments

See deficiency #11a.

Deficiency #11c is resolved.

CBTS Deficiency #12b

Additional residue data for pecans are needed which represent the proposed use [i.e. Data are needed which reflect both the minimum spray volumes (100 and 200 gals. by ground and 3 gals. by air) and the 7-day spray interval]. Studies on pecans representing the proposed use should be made available from the area of AL/GA/LA/MS and from the area of NM/TX/OK. Several representative samples from each study should be analyzed.

Petitioner's Response to Deficiency #12b

No new data are being submitted at this time. The label has been revised to recommend applications in 300 gallons of finished spray per acre with a 15 day spray interval.

CBTS Comments

Although the petitioner states that the label has been revised to recommend applications in 300 gallons of finished spray, the only change observed is the addition of a 15 day spray interval. No change was made to the minimum spray volumes. Also, the old label for pecans specified a PHI of 21 days and this PHI is not specified in the new submitted label. A 21 day PHI should be added to the proposed label for pecans. A revised Section B is needed.

Deficiency #12b is unresolved.

CBTS Deficiency #12c

The additional aerial data which were provided for pecans do not reflect the proposed minimum spray interval of 7 days.

Petitioner's Response to Deficiency #12c

The data generated relative to pecans will support use directions that recommend a 15 day spray interval. The label has been revised accordingly.

CBTS Comments

See deficiency 12b.

Deficiency #12c is unresolved.

CBTS Deficiency #12d

The revised labels for pecans specify minimum spray intervals of 7 days. However, this spray interval is not well represented by the residue data, which reflect spray intervals of 7 to 66 days. Additional residue data representing the 7-day spray interval are needed as stated in 12 (b).

Petitioner's Response to Deficiency #12d

The data generated relative to pecans will support use directions that recommend a 15 day spray interval. The proposed label has been revised accordingly.

CBTS Comments

The existing residue data for pecans support a 15 day spray interval between applications. However, this deficiency remains unresolved for the reasons stated in deficiency 12b.

Deficiency #12d is unresolved.

cc: RF, Circu., José J. Morales, M. Flood, E. Haeberer, PP#6F3454
7509C: Reviewer (JJM): CM#2: Rm 804-Q: 305-5010: typist (JJM): 3/7/94
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