Shaughnessy No.: 128825
Date Out of EAB: FEB 10 1988

To: George LaRocca
Product Manager PM #15
Registration Division (TS-767)

in RD 2/23/88

From: Emil Regelman, Supervisory Chemist
Environmental Chemistry Review Section #3
Exposure Assessment Branch/HED (TS-769C)

Thru: Paul F. Schuda, Chief
Exposure Assessment Branch/HED (TS-769C)

Attached, please find the EAB review of...

Reg./File # : 6F3453

Chemical Name: Bifenthrin

Type Product : Insecticide

Product Name : CAPTURE

Company Name : FMC Corporation

Purpose : Review registrant's response to EAB's review dated August 7, 1987.

Action Code: 332 EAB #(s): 80295

Date Received: 1/6/88 Total Reviewing Time: 2 days

Date Completed: 2/9/88

Monitoring Study Requested: _____

Monitoring Study Volunteered: _____

Deferrals to: X Ecological Effects Branch

X Residue Chemistry Branch

____ Toxicology Branch

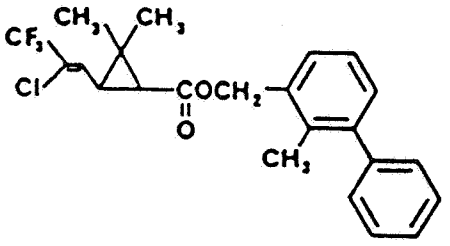
1. CHEMICAL:

chemical name: (2-methyl-1,1'-biphenyl-3-yl)methyl trans-4-(2-chloro-3,3,3-trifluoro-1-propenyl)-3,3-dimethylcyclopropanecarboxylate

common name: Bifenthrin

trade name: Capture

structure:



physical/chemical properties:

molecular formula:	$C_{22}H_{22}O_2F_3Cl$
molecular weight:	422.88
physical state:	solid
melting point:	57-64°C (technical)
vapor pressure:	1.81×10^{-7} torr at 25°C
solubility:	In water, <0.1ppb; soluble in most organic solvents, slightly soluble in n-heptane and methanol.

2. TEST MATERIAL:

Not applicable. No studies were submitted.

3. STUDY/ACTION TYPE:

FMC's response to EAB's review dated August 7, 1987.

4. STUDY IDENTIFICATION:

Robinson, R.A., et al. "FMC Corporation Response to Environmental Assessment Branch Review of Data Pertaining to the Use of Bifenthrin on Cotton (pp # 6F3453), peaches, pears, pecans, walnuts, strawberries (pp # 6F3454) and corn. Submitted by FMC Corp on 11/19/87. Received by EPA on 11/19/87. Accession number 404140-01.

5. REVIEWED BY:

Dana Spatz
Chemist
EAB/HED/OPP

Date: FEB 10 1988

6. APPROVED BY:

Emil Regelman
Supervisory Chemist
EAB/HED/OPP

Date: FEB 10 1988

7. CONCLUSIONS:

I. Confined Rotational Crops: (Tables 1-6)

Although the residues in crops other than wheat straw were not characterized, this study will be acceptable to EAB if the total residues found in the crops are at a level that is below the tolerances that are to be set by RCB. Note that the study supports an application rate of 0.5 lb ai/A, not 1 lb ai/A as is stated on the product label.

If the residue levels are considered excessive, then the study must be repeated with a longer treatment to planting interval.

II. Laboratory Volatility: (Tables 7-8)

This study (acc. #264642), is unacceptable and hence, does not fulfill EPA requirements for registering pesticides for the following reasons:

a. No soil measurements were taken, therefore, a material balance was not available, nor was there an application rate confirmation.

b. The study consisted of only two sampling intervals.

c. The trapping efficiency was 132%.

d. During the length of the study, there was no apparent decline in volatilization.

e. A sandy soil with a low kd value was not used.

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III. Photodegradation in Water:

After reviewing the clarifications made by the registrant, this study is deemed acceptable in fulfilling the requirements for registering pesticides.
The results of this study, (acc. #264642), indicate that bifenthrin, in water, is stable to photolysis under natural sunlight. The half-life is between 209 and 300 days.

This study was originally rejected by Dynamac, however, the registrant's response to the review afforded the information necessary to validate the study. The study was originally rejected because the cosolvent concentration was 30% by volume, the test solution was not buffered, and the temperature was not constant. As explained in the registrant's response, the amount of cosolvent could not have been less than 30%, due to the insolubility of bifenthrin. Secondly, although the solutions were not buffered, bifenthrin is stable at pH 5-9 and the dark control samples were stable throughout the study. Finally, the registrant did make an effort to maintain a constant temperature of 25°C; however, it becomes almost impossible to do so in an outdoor study. The average temperature was, however, maintained at a range approximating 25°C.

IV. Fish Accumulation: (Tables 9-10)

The results of this study indicate that bifenthrin does bioaccumulate in fish. Bioconcentration factors on Day 42 were 2100x (1.9 ppb, edible), 8720x (7.85 ppb, non-edible), and 6090x (5.48 ppb, whole fish). Concentration of [^{14}C] residues in water ranged from 0.006 to 0.0014 ppb during the 42 Day exposure study. After 42 days of depuration, [^{14}C] residues were 0.81 ppb in edible tissue, 3.52 ppb in non-edible tissue, and 2.92 ppb in whole fish.

Although bioaccumulation levels did not plateau, this study is acceptable to EAB for registering pesticides, pending concurrence by EEB.

V. Aerobic Soil Metabolism:

This data requirement was partially satisfied according to a memorandum from Samuel Creeger (EAB) to John Tice (SIS) dated May 17, 1985, pending an explanation about the differences in half-lives between alcohol-labeled and acid-labeled bifenthrin.

The registrant has, in this submission, adequately explained the differences in half-lives. According to the registrant,

"some degree of diversity in data can be attributed to experimental variability", since the studies were conducted on different batches of common soil types. Also, because of the slow degradation rates, experimental variability can have a pronounced effect on the calculated rate constants.

The aerobic soil metabolism study requirement has been fulfilled. The half-life ranges from 97 to 250 days.

VI. Terrestrial Field Dissipation: (Tables 11-12)

This data requirement remains unfulfilled. It appears that in the Stearns study, contamination by the upper layer may have occurred. This could have led to the curious results for the 6-12'' layer. In the Pejovich study, the extent of leaching was again not defined, for residues of bifenthrin were detected at levels as high as 0.13 ppm in the 6-12'' samples after 7 days posttreatment. Therefore, it is unknown as to whether or not bifenthrin leached past the 12 inch cutoff, and hence, went undetected.

8. RECOMMENDATIONS:

The Photodegradation in Water study and the Aerobic Soil Metabolism study are acceptable in fulfilling the requirements for registering pesticides.

The registrant should repeat the Laboratory Volatility study and the Terrestrial Field Dissipation study. They remain as data gaps.

The Confined Rotational Crop study will be acceptable pending concurrence by RCB. The Fish Accumulation study will be acceptable pending concurrence by EEB.

9. BACKGROUND:

EUP's were granted for strawberries, walnuts, corn, pecans, pears, peaches, and orchard crops on April 28, 1986.

This submission is FMC's response to EAB's review dated August 7, 1987.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

Not applicable. No studies were submitted.

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11. COMPLETION OF ONE-LINER:

Not applicable.

12. CBI APPENDIX:

Not applicable.

Confined Rotational Crop Data

Table 1

Table 1. [^{14}C]Residues in lettuce and soil from pots of sandy loam soil treated with phenyl-labeled [^{14}C]bifenthrin (radiochemical purity 97.3%) at 0.5 lb ai/A.

Treatment-to-planting interval (days)	Sample	Sampling interval	Total (ppm)	Organic fraction					Aqueous fraction	Unextractable
				Bifenthrin	4'-OH Bifenthrin[a]	BP acid[b]	BP alcohol[c]	Unidentified[d]		
				% of the recovered						
--	Soil 0-3 inches	Treatment	2.48	95.3	--	--	--	1.8	0.1	2.8
30	Soil 0-3 inches	Planting	0.34	80.4	2.2	2.0	0.4	3.2	0.8	10.9
		Harvest	1.33	77.8	6.9	0.9	0.6	4.0	0.4	9.4
	3-15 inches	Harvest	0.07	--	--	--	--	--	--	--
	Lettuce (whole)	Immature	0.016	--	--	--	--	--	--	--
		Mature	0.120	--	--	--	--	--	--	--
66	Soil 0-3 inches	Planting	1.20	77.7	3.9	0.9	0.4	4.9	0.8	11.4
		Harvest	0.59	76.5	5.0	0.4	0.7	4.6	0.3	12.5
	3-15 inches	Harvest	0.08	--	--	--	--	--	--	--
	Lettuce (whole)	Immature	0.027	--	--	--	--	--	--	--
		Mature	0.021	--	--	--	--	--	--	--
120	Soil 0-3 inches	Planting	0.430	46.9	9.4	6.8	1.2	7.0	1.1	27.6
		Harvest	0.430	28.1	10.9	1.6	1.4	8.4	1.3	48.3
	3-15 inches	Harvest	0.050	--	--	--	--	--	--	--
	Lettuce (whole)	Immature	0.026	--	--	--	--	--	--	--
		Immature	0.010	--	--	--	--	--	--	--
		Mature	0.014	--	--	--	--	--	--	--

[a] 3-(4'-Hydroxyphenyl)-2-methylbenzyl (+)cis-4-(2-chloro-3,3,3-trifluoro-1-propenyl)-3,3-dimethylcyclopropanecarboxylate; 4'-OH bifenthrin.

[b] 2-Methyl-3-phenylbenzoic acid; BP acid.

[c] 2-Methyl-3-phenylbenzyl alcohol; BP alcohol.

[d] Six products were isolated but not identified; each comprised <2% of the total [^{14}C]residues.

CONFINED ROTATIONAL CROP DATA TABLE 2

Table 2. [^{14}C]Residues in sugar beets and soil from pots of sandy loam soil treated with phenyl-labeled [^{14}C]bifenthrin (radiochemical purity >97.3%) at 0.5 lb ai/A.

Treatment-to-planting interval (days)	Sample	Sampling interval	Total (ppm)	Organic fraction					Aqueous fraction	Unextractable
				Bifenthrin	4'-OH Bifenthrin[a]	BP acid[b]	BP alcohol[c]	Unidentified[d]		
				% of the recovered						
--	Soil 0-3 inches	Treatment	2.48	95.3	--	--	--	1.8	0.1	2.1
30	Soil 0-3 inches	Planting	0.34	80.4	2.2	2.0	0.4	3.2	0.8	10.9
		Harvest	0.53	40.4	5.4	0.3	0.6	7.2	0.1	45.3
	3-15 inches	Harvest	0.07	--	--	--	--	--	--	--
	Sugar beet	Immature	0.036	--	--	--	--	--	--	--
		Immature	0.031	--	--	--	--	--	--	--
		Tops	0.009	--	--	--	--	--	--	--
		Roots	0.009	--	--	--	--	--	--	--
66	Soil 0-3 inches	Planting	1.20	77.7	3.9	0.9	0.4	4.9	0.8	10.9
		Harvest	0.36	36.9	4.7	0.6	0.7	6.7	1.8	48.7
		Harvest	0.03	--	--	--	--	--	--	--
	Sugar beet	Immature	0.065	--	--	--	--	--	--	--
		Immature	0.021	--	--	--	--	--	--	--
		Tops	0.007	--	--	--	--	--	--	--
		Roots	0.008	--	--	--	--	--	--	--
120	Soil 0-3 inches	Planting	0.43	46.9	9.4	6.8	1.2	7.0	1.1	27.6
		Harvest	1.18	30.9	3.6	1.1	0.6	6.7	1.7	55.4
	3-15 inches	Harvest	0.10	--	--	--	--	--	--	--
	Sugar beet	Immature	0.049	--	--	--	--	--	--	--
		Immature	0.021	--	--	--	--	--	--	--
		Tops	0.004	--	--	--	--	--	--	--
		Roots	0.005	--	--	--	--	--	--	--

[a] 3-(4'-Hydroxyphenyl)-2-methylbenzyl (+)cis-4-(2-chloro-3,3,3-trifluoro-1-propenyl)-3,3-dimethylcyclopropanecarboxylate; 4'-OH bifenthrin.

[b] 2-Methyl-3-phenylbenzoic acid; BP acid.

[c] 2-Methyl-3-phenylbenzyl alcohol; BP alcohol.

[d] Six products were isolated but not identified; each comprised <2% of the total [^{14}C]residues.

CONFINED ROTATIONAL CROP DATA

TABLE 3

Table 3. [^{14}C]Residues in wheat and soil from pots of sandy loam soil treated with phenyl-labeled [^{14}C]bifenthrin (radiochemical purity >97.3%) at 0.5 lb ai/A.

Treatment-to-planting interval (days)	Sample	Sampling interval	Total (ppm)	Organic fractions: Bifenthrin	4'-OH Bifenthrin[a]	BP acid[b]	BP alcohol[c]	BP aldehyde[d]	Unidentified[e]	Aqueous fraction	Unextractable
				% of the recovered							
--	Soil 0-3 inches	Treatment	2.480	95.3	--	--	--	--	1.8	0.1	2.8
30	Soil 0-3 inches	Planting	0.340	80.4	2.2	2.0	0.4	--	3.2	0.8	10.9
		Harvest	0.280	38.1	3.4	0.9	0.9	--	12.5	5.5	38.7
	3-15 inches	Harvest	0.080	--	--	--	--	--	--	--	--
	Wheat	Immature	0.012	--	--	--	--	--	--	--	--
		Immature	0.014	--	--	--	--	--	--	--	--
		Grain	0.016	--	--	--	--	--	--	--	--
		Straw	0.094	7.5	1.3	1.5	1.2	0.6	36.1	12.2	39.7
66	Soil 0-3 inches	Planting	1.200	77.7	3.9	0.9	0.4	--	4.9	0.8	11.4
		Harvest	0.780	48.7	5.8	0.6	0.9	--	6.7	1.0	36.3
	3-15 inches	Harvest	0.070	--	--	--	--	--	--	--	--
	Wheat	Immature	0.019	--	--	--	--	--	--	--	--
		Immature	0.021	--	--	--	--	--	--	--	--
		Grain	0.025	--	--	--	--	--	--	--	--
		Straw	0.160	10.7	2.9	1.6	1.3	0.8	22.6	13.5	46.5
137	Soil 0-3 inches	Planting	0.430	46.9	9.4	6.8	1.2	--	7.0	1.1	27.6
		Harvest	0.600	32.9	5.6	1.5	0.9	--	8.1	0.9	50.1
	3-15 inches	Harvest	0.040	--	--	--	--	--	--	--	--
	Wheat	Immature	--	--	--	--	--	--	--	--	--
		Immature	0.021	--	--	--	--	--	--	--	--
		Grain	0.032	--	--	--	--	--	--	--	--
		Straw	0.193	5.3	1.2	2.2	0.8	0.3	27.2	15.3	47.7

[a] 3-(4'-Hydroxyphenyl)-2-methylbenzyl (+)cis-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-3,3-dimethylcyclopropanecarboxylate; 4'-OH bifenthrin.

[b] 2-Methyl-3-phenyl benzoic acid; BP acid.

[c] 2-Methyl-3-phenylbenzyl alcohol; BP alcohol.

[d] 2-Methyl-3-phenylbenzaldehyde; BP aldehyde.

[e] Includes unidentified from both the acetone and ethyl acetate (straw only) fractions.

CONFINED ROTATION #
CROP DATA
TABLE 4

Table 4. [^{14}C]Residues in lettuce and soil from pots of sandy loam soil treated with cyclopropyl-labeled [^{14}C]bifenthrin (radiochemical purity 98%) at 0.5 lb ai/A.

Treatment-to-planting interval (days)	Sample	Sampling interval	Total (ppm)	Organic fraction				Aqueous fraction	Unextractable
				Bifenthrin	4'-OH Bifenthrin[a]	TFP acid[b]	Unidentified[c]		
				% of the recovered					
--	Soil 0-3 inches	Treatment	1.17	96.4	ND	ND	2.5	0.3	0.8
30	Soil 0-3 inches	Planting	1.08	85.0	2.3	1.4	5.8	0.2	5.3
		Harvest	0.90	67.8	7.8	2.2	8.3	2.4	11.5
	3-15 inches	Harvest	0.08	--	--	--	--	--	--
	Lettuce (whole)	Immature	0.019	--	--	--	--	--	--
		Mature	0.014	--	--	--	--	--	--
66	Soil 0-3 inches	Planting	1.43	80.3	4.1	0.9	6.9	0.3	7.5
		Harvest	0.69	41.6	14.1	9.8	9.6	1.9	23.0
	3-15 inches	Harvest	0.25	--	--	--	--	--	--
	Lettuce (whole)	Immature	1.43	--	--	--	--	--	--
		Immature	0.69	--	--	--	--	--	--
		Mature	0.25	--	--	--	--	--	--
120	Soil 0-3 inches	Planting	0.021	55.5	5.8	5.2	11.7	1.1	20.7
		Harvest	0.026	35.7	8.9	9.0	15.7	5.0	25.7
	3-15 inches	Harvest	0.029	--	--	--	--	--	--
	Lettuce (whole)	Immature	0.019	--	--	--	--	--	--
		Immature	0.009	--	--	--	--	--	--
		Mature	0.017	--	--	--	--	--	--

[a] 3-(4'-Hydroxyphenyl)-2-methylbenzyl (+)cis-4-(2-chloro-3,3,3-trifluoro-1-propenyl)-3,3-dimethylcyclopropanecarboxylate; 4'-OH bifenthrin.

[b] cis,trans-4-(2-Chloro-3,3,3-trifluoro-1-propenyl)-3,3-dimethylcyclopropanecarboxylic acid; TFP acid.

[c] Eight products were isolated but not identified; each comprised <2% of the total [^{14}C]residue.

CONFINED ROTATIONAL CROP DATA

TABLE 5

Table 5. [^{14}C]Residues in sugar beets and soil from pots of sandy loam soil treated with cyclopropyl-labeled [^{14}C]bifenthrin (radiochemical purity 98%) at 0.5 lb ai/A.

Treatment-to-planting interval (days)	Sample	Sampling interval	Total (ppm)	Organic fraction				Aqueous fraction	Unextractable
				Bifenthrin	4'-OH Bifenthrin[a]	TFP acid[b]	Unidentified[c]		
				% of the recovered					
--	Soil 0-3 inches	Treatment	1.17	96.4	ND	ND	2.5	0.3	0.8
30	Soil 0-3 inches	Planting	1.08	85.0	2.3	1.4	5.8	0.2	5.3
		Harvest	0.81	59.3	5.0	0.8	5.9	5.1	23.9
	3-15 inches	Harvest	0.08	--	--	--	--	--	--
	Sugar beet	Immature	0.024	--	--	--	--	--	7.5
		Immature	0.023	--	--	--	--	--	--
		Tops	0.031	--	--	--	--	--	39.7
		Roots	0.021	--	--	--	--	--	--
66	Soil 0-3 inches	Planting	1.43	80.3	4.1	0.9	6.9	0.3	--
		Harvest	0.77	37.2	5.7	2.3	9.4	5.7	--
		Harvest	0.05	--	--	--	--	--	--
	Sugar beet	Immature	0.058	--	--	--	--	--	--
		Immature	0.035	--	--	--	--	--	--
		Tops	0.023	--	--	--	--	--	--
		Roots	0.019	--	--	--	--	--	
120	Soil 0-3 inches	Planting	0.72	55.5	5.8	5.2	11.7	1.1	20.7
		Harvest	0.52	19.5	4.6	1.6	13.2	3.8	57.3
	3-15 inches	Harvest	0.15	--	--	--	--	--	--
	Sugar beet	Immature	0.052	--	--	--	--	--	-
		Immature	0.027	--	--	--	--	--	--
		Tops	0.017	--	--	--	--	--	--
		Roots	0.008	--	--	--	--	--	--

[a] 3-(4'-Hydroxyphenyl)-2-methylbenzyl (+)cis-4-(2-chloro-3,3,3-trifluoro-1-propenyl)-3,3-dimethylcyclopropanecarboxylate; 4'-OH bifenthrin.

[b] cis,trans-4-(2-Chloro-3,3,3-trifluoro-1-propenyl)-3,3-dimethylcyclopropanecarboxylic acid; TFP acid.

[c] Eight products were isolated but not identified; each comprised <2% of the total [^{14}C]residue.

CONFINED ROTATIONAL CROP DATA
TABLE 6

Table 6. [^{14}C]Residues in wheat and soil from pots of sandy loam soil treated with cyclopropyl-labeled [^{14}C]bifenthrin (radiochemical purity 98%) at 0.5 lb ai/A.

Treatment-to-planting interval (days)	Sample	Sampling interval	Total (ppm)	Organic fractions					Unextractable
				Bifenthrin	4'-OH Bifenthrin[a]	TFP acid[b]	Unidentified[c]	Aqueous fraction	
				% of the recovered					
--	Soil 0-3 inches	Treatment	1.17	96.4	ND	ND	2.5	0.3	0.8
30	Soil 0-3 inches	Planting	1.08	85.0	2.3	1.4	5.8	0.2	5.3
		Harvest	0.42	26.7	9.1	3.1	10.4	2.6	48.1
	3-15 inches	Harvest	0.11	--	--	--	--	--	--
	Wheat	Immature	0.032	--	--	--	--	--	--
		Immature	0.033	--	--	--	--	--	--
		Grain	0.035	--	--	--	--	--	--
		Straw	0.247	2.9	0.5	4.6	63.1	8.5	20.5
66	Soil 0-3 inches	Planting	1.43	80.3	4.1	0.9	6.9	0.3	7.5
		Harvest	0.51	40.8	11.6	1.5	11.1	2.8	32.2
	3-15 inches	Harvest	0.08	--	--	--	--	--	--
	Wheat	Immature	0.032	--	--	--	--	--	--
		Immature	0.020	--	--	--	--	--	--
		Grain	0.042	--	--	--	--	--	--
		Straw	0.247	7.0	1.4	6.7	56.4	10.3	18.1
137	Soil 0-3 inches	Planting	0.72	55.5	5.8	5.2	11.7	1.1	20.7
		Harvest	0.42	67.5	2.2	1.2	9.4	0.4	19.3
	3-15 inches	Harvest	0.06	--	--	--	--	--	--
	Wheat	Immature	0.039	--	--	--	--	--	--
		Immature	0.053	--	--	--	--	--	--
		Grain	0.049	--	--	--	--	--	--
		Straw	0.312	7.4	1.4	2.9	63.8	9.3	15.3

[a] 3-(4'-Hydroxyphenyl)-2-methylbenzyl (+)cis-4-(2-chloro-3,3,3-trifluoro-1-propenyl)-3,3-dimethylcyclopropanecarboxylate; 4'-OH bifenthrin.

[b] cis,trans-4-(2-Chloro-3,3,3-trifluoro-1-propenyl)-3,3-dimethylcyclopropanecarboxylic acid; TFP acid.

[c] Includes unidentified from both the acetone and ethyl acetate (straw only) fractions.

LAB VOLATILITY DATA
TABLE 7

Table 1. Effect of air flow and temperature on the volatility (x 10^5 µg per cm^2 per hour) and air concentration (µg/m^3) of bifenthrin from loam soil at 75% soil moisture capacity treated with phenyl-labeled [^{14}C]bifenthrin (formulated with Capture 2 lb/gal EC) at 0.1 lb ai/gallon.

Air flow (L/minute)	5.7		11.3		16.7	
	Sampling interval (hours)					
	18	39	18	39	18	39
			25° C			
Volatility	7.940	8.010	17.590	15.400	21.440	19.040
Air concentration	0.135	0.136	0.151	0.132	0.124	0.110
			40° C			
Volatility	25.500	21.420	46.380	38.350	63.400	50.890
Air concentration	0.433	0.363	0.397	0.329	0.367	0.295

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LAB VOLATILITY
DATA
TABLE 8

Table 2. Effect of soil moisture on the volatility (x 10^5 µg per cm^2 per hour) and air concentration (µg/m^3) of bifenthrin from loam soil treated with phenyl-labeled [^{14}C]bifenthrin (formulated with Capture 2 lb/gal EC) at 0.1 lb ai/gallon. The incubation temperature was 25°C, and the air flow rate was 11.3 L/minute.

	Sampling interval (hours)	
	0-18	18-39
	0% Soil moisture capacity	
Volatility	11.63	10.66
Air concentration	0.100	0.091
	25% Soil moisture capacity	
Volatility	13.09	12.11
Air concentration	0.112	0.104
	75% Soil moisture capacity	
Volatility	13.65	12.84
Air concentration	0.117	0.110

FISH ACCUMULATION

TABLE 9

Table 1. Total [^{14}C]residues in (ppb) water and tissues of bluegill sunfish treated with phenyl ring-labeled [^{14}C]bifenthrin (radiochemical purity >96%) during a 42-day exposure and 42-day depuration period.[a]

Sampling interval (days)	Water (ppb)	Edible		Non edible		Whole fish	
		ppb	BCF	ppb	BCF	ppb	BCF
			Exposure				
0	0.0006	ND	--	ND	--	ND	--
3	0.0006	ND	--	0.70	1170	0.50	833
7	0.0008	0.43	614	2.18	3110	1.00	1430
14	0.0008	1.01	1440	3.83	5470	2.88	4110
21	0.0014	1.56	1950	5.25	6560	4.17	5210
28	0.0012	1.47	1630	5.74	6380	3.62	4020
35	0.0011	1.93	2140	7.73	8590	3.88	4310
42	0.0008	1.90	2110	7.85	8720	5.48	6090
			Depuration				
0	--	1.90	--	7.85	--	5.48	--
1	ND	1.70	--	7.64	--	ND	--
3	ND	1.53	--	7.32	--	ND	--
7	ND	1.69	--	6.82	--	3.28	--
10	ND	1.62	--	5.88	--	4.34	--
14	ND	1.03	--	6.30	--	3.64	--
21	ND	0.86	--	4.60	--	3.08	--
28	ND	1.14	--	5.01	--	3.18	--
35	ND	0.87	--	4.30	--	2.96	--
42	ND	0.81	--	3.52	--	2.92	--

[a] Data are averages of two samples for whole fish and three samples of edible fish.

[b] ND = not detected (detection limits: edible = >0.052 to <0.25 ppb; non-edible = >0.042 to <0.17 ppb whole body = >0.060 to <0.49 ppb.

[c] Daily bioconcentration factor (BCF) calculated by dividing the concentration of [^{14}C]residues measured in the tissue, by the mean measured water concentration. The mean measured water concentration was calculated using all mean measured water concentrations prior to and including the respective test day.

FISH ACCUMULATION

TABLE 10

Table 2. Distribution of radioactivity (% of recovered) in water and tissues of bluegill sunfish exposed to phenyl ring-labeled [^{14}C]bifenthrin (radiochemical purity >96%) at 0.0009-0.019 ppb.

Sampling interval (days)	Total (ppb)	Bifenthrin	Degradates			Unextractable
			4'-OH Bifenthrin[a]	BP alcohol[b]	Unknowns	
		%				
Edible tissue (fillet)						
52	5.88	86.0	2.8	ND[d]	4.7	6.5
63	15.23	70.2	3.6	ND	4.8	21.4
Inedible tissue (viscera)						
52	27.09	69.7	2.9	ND	4.0	23.4
63	63.74	66.8	3.2	0.5	6.3	23.2
Water						
0, 14, 42 (Pooled)	NR[c]	56	ND	ND	26	--

[a] 3-(4'-Hydroxyphenyl)-2-methylbenzyl (+)cis-4-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate.

[b] 2-methyl-3-phenylbenzyl alcohol.

[c] Not reported, the average was ~0.0009 ppb.

[d] Not detected; the detection limit was not reported.

TERRESTRIAL FIELD DISSIPATION TABLE 11

Table 3. Bifenthrin (ppm) in loamy sand soil (Georgia) and loam soils (Arkansas, California, Illinois) treated with bifenthrin (Capture 2 lb/gal EC) at 2 lb ai/A.

Approximate treatment-to-sampling interval (days)	Sampling depth (inches)							
	Georgia		Arkansas		California		Illinois	
	0-6	6-12	0-6	6-12	0-6	6-12	0-6	6-12
0	1.45	ND[a]	1.30	0.45	0.79	0.21	0.58	0.14
7	0.82	0.08	1.40	0.01	0.35	0.18	1.75	0.02
14	0.85	0.08	1.64	0.16	0.37	0.07	1.66	0.11
30	0.39	0.06	0.78	0.06	0.14	0.06	1.62	0.16
90	0.34	0.03	1.12	ND	0.08	0.04	0.28	0.02
180	0.44	ND	0.44	ND	0.38	0.05	0.23	0.02
270	0.23	ND	--	--	0.17	0.15	0.42	0.01
360	0.09	ND	0.05	ND	0.07	0.06	0.13	ND

[a] Not detected; the detection limit was 0.01 ppm.

TERRESTRIAL FIELD DUSIPATION
TABLE 12

Table 2. Bifenthrin (ppm) in loam soils treated with a single broadcast application of bifenthrin (Brigade, 10% WP) at 2 lb ai/A.

Treatment-to-sampling interval (days)	Sampling depth (inches)			
	Illinois		Arkansas	
	0-6	6-12	0-6	6-12
0	0.65	--	0.92	--
7	0.66	0.13	0.85	0.06
14	0.44	0.05	1.06	0.02
30	0.28	0.04	--	--
31	--	--	0.50	0.02
90	0.28	ND[a]	--	--
179	--	--	0.25	ND
183	0.18	0.02	--	--
270	--	--	0.16	ND
325	0.11	0.02	--	--
360	0.06	ND	0.13	ND

[a] Not detected; the detection limit was 0.01 ppm.

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II. DISCUSSION

1. Confined Crop Rotation (Guideline #165-1)
Bixler, T.A., FMC 54800 Confined Rotational Crop Study. FMC Report No. P-1372, April 16, 1986. Unpublished report prepared by FMC Corporation. Originally submitted August 29, 1986 in support of Bifenthrin Technical (EPA Reg. No. 279-3055). Amended Registration Application/Tolerance Petition; Cottonseed, Milk, Meat (fat and meat by-products). Tolerance Petition No. 6F3453. EPA Accession No. 264642.

A. Agency Concern - The maximum single rate of application is 0.2 lb. ai/A; however, the label states that up to a total of 1 lb. ai/year may be applied. Only 0.5 lb. ai/A was applied in the study.

FMC Response - The study was run at 0.5 lb. ai/A even though a maximum foliar treatment rate of 1.0 lb. ai/a was targeted as a maximum anticipated seasonal use rate. FMC assumed that plant foliage would intercept at least 50% of the spray. There is evidence to support the thesis that less than half the active ingredient applied in a foliar spray actually reaches the ground. For example, in a study conducted by FMC (Pounce Aerial Deposition Study, B.M. McKay, FMC, 1981) (Ref. 1), values were obtained to show that when comparing deposition of Pounce on mylar sheets placed in the top canopy of cotton plants vs. mylar sheets placed in the row middle, (i.e., on the soil), the deposition on the soil was less than 50% of the total deposited (29-38% of the total deposited). Photodocumentation of the fields treated indicate that about half the field was covered with plants at time of treatment - indicating that sample deposition favored plant surface in spite of a maximized soil surface area. In another study (Clower, LSU, 1983) (Ref. 2), the deposition of oil - and water-based ULV sprays of permethrin (Pounce) were examined with cards placed in the top plant canopy and the soil. The soil showed much lower deposition than the top canopy, with numbers ranging from 11-28% of the total material deposited. Thus the application of 0.5 lb. ai/A to the soil for a crop rotation study provides even more ai to the soil than would be expected from the typical foliar use rate of a 1 lb. ai/A and a crop rotation study at a soil treatment rate of 0.5 lb. ai/A should support a foliar use rate of 1 lb. ai/A for bifenthrin.

B. Agency Concern - The study was not conducted for 365 days. Residues were present at the 120 day interval.

FMC Response - Data from confined crop rotation are used to determine the amount and nature of pesticide residues in rotational crops. Agency guidelines do not specify an exact interval over which the study must be conducted. One year is viewed to be the maximum interval for aging of soil. Based on FMC's experience with other pyrethroids and specifically on results obtained from crop rotation studies with analogous materials, 120 days was judged to be a satisfactory cut-off interval.

Results from the bifenthrin confined crop rotation study show little difference in radioactive residue accumulation over the rotational intervals studies - i.e., 30, 60, and 120 days after soil treatment. In fact, the study confirmed plant (cotton, corn, apple) metabolism studies conducted with the chemical which showed a lack of systemicity (uptake, translocation). In addition, results were similar to those obtained with other pyrethroids - e.g., permethrin and cypermethrin which possess crop rotation restrictions of less than one year.

C. Agency Concern - Residues in lettuce, sugar beets and wheat grain were not characterized.

FMC Response - Residues in commodities other than wheat straw were not characterized because none exceeded 0.05 ppm (bifenthrin equivalents) and thus were judged to be not significant in magnitude to warrant further examination. Attempts to generate meaningful results would be pointless in view of the low levels of radioactive residue.

D. Agency Concern - Values for control soils were not reported.

FMC Response - The purpose for control tests in this study was to assess the level of background carbon-14 radiocarbon levels in crops which could potentially impact results of the study. Radioactivity background in soil was not (nor should it have been) a concern issue. Analysis of control plants indicated negligible carbon-14 background levels. Thus levels in control soil must have been similarly negligible in content or, at the very least, in plant uptake potential. Even if control soils had been assayed for background radiation, the data would not have impacted the results of this study.

E. Agency Concern - Recovery efficiencies from fortified soil and plant samples were not reported.

FMC Response - Recovery data for treated soil/plant systems can be derived from a comparison of total carbon-14 recovered via extraction versus radiocarbon values in the matrix as measured by combustion analysis. Combustion assay data provide an absolute value for comparison unlike nonradiolabelled residue analyses which often require an evaluation of various extraction methods. "Zero time" soil extraction data, which may be viewed as a fortification, indicated acceptable levels of recovery for both parent chemical and total radiocarbon. In addition, the soil extraction method used in this study was also employed in FMC's soil metabolism efforts (Ref. 3, Ref. 4, Ref. 5). Radiocarbon recoveries from soil control fortification consistently exceeded 90%. The wheat straw extraction technique of acetone blend has been used successfully in other plant matrices (Ref. 6) for the extraction of bifenthrin.

In summary, the study submitted on confined crop rotation supports the premise of limited systemicity for bifenthrin as well as the adequacy of a 120 day (or less) rotational restriction interval as has been observed for other pyrethroids of similar chemical nature.

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2. Laboratory Volatility (Guideline #163-2)

Ferraro, C.F. and Zuccarello, W.J. FMC 54800 Laboratory Volatility Study, Report No. P-1463, August 15, 1986. Unpublished report prepared by FMC Corporation. Originally submitted August 29, 1986 in support of Bifenthrin Technical (EPA Reg. No. 279-3055). Amended Registration Application/Tolerance Petition; Cottonseed, Milk, Meat (fat and meat by-products). Tolerance Petition No. 6F3453. EPA Accession No. 264642.

A. Agency Concerns - Soil was not analyzed for bifenthrin, and the material balance was incomplete.

FMC Response - The bifenthrin was quantitatively applied to the soil. A pipetted quantity of an analyzed emulsion of the bifenthrin was sprayed onto the soil surfaces followed by thorough rinsing of the small laboratory sprayer. The trapping efficiency of the traps was determined by placing a quantitative amount of bifenthrin onto the trap, and passing air through the trap for 18 hours. At the end of this time, the bifenthrin was extracted and analytically determined. A quantitative recovery was found. In addition, as reported in this study, it was determined experimentally that there was no "strike-through" of bifenthrin through the polyurethane plugs. When a second trap was placed in series, the amount of bifenthrin present on the first trap (after the passage of air for an 18 hour period) was 97.6% of the total bifenthrin recovered from both traps. Because of the initial quantitative transfer of bifenthrin to the soil coupled with excellent trapping efficiencies, it did not appear necessary to measure the amount of bifenthrin remaining on the soil at the conclusion of the various experiments.

Prior to designing the protocol for the experimental procedures, the four references which were provided in the 1982 Pesticide Assessment Guidelines, Subdivision N, Section 163-2 "Laboratory Volatility Studies" were examined. Three of the references were stated to be "useful for protocol development" and one reference was "a review of reported methods for laboratory investigations of pesticides in air". In each of the references, trapping techniques are described to quantitatively determine the amount of pesticide that volatilizes from the soil. An analysis of the pesticide remaining on the soil was not carried out in any of the referenced studies. The conclusions reached in the references cited above indicated that volatility data could be calculated from the measured values of the trapped insecticide and therefore was not needed.

B. Agency Concern - Vapor pressure, solubility in water, and relative humidity in the volatilization flasks were not reported.

FMC Response - The value for the vapor pressure of bifenthrin was not included in the subject report. The vapor pressure of bifenthrin has been measured by FMC over a range of temperatures (Ref. 7). The expression for the vapor pressure is:

$$\text{Log } P = 12.3216 - 5681/T$$

where P is the vapor pressure of FMC 54800 in torr and T is the temperature in degrees Kelvin. Thus at 25 and 40°C, the calculated vapor pressures are 1.81×10^{-7} and 1.48×10^{-6} torr, respectively.

The value for the solubility of FMC 54800 in water was also not included in the subject report. The value had been measured and reported by FMC (Ref. 8). The solubility is <0.1 ug/L (ppb).

The relative humidity of the air was not measured in the subject report. The relative humidity of the air entering the volatilization chambers, however, had been measured at 25 and 40°C using a humidity-temperature meter during a study identical to the bifenthrin study with the exception that the pesticide investigated was carbofuran. The measured relative humidity values in the chamber were 80% regardless of the temperature or wind velocity readings.

C. Agency Concern - The K_d soil adsorption coefficient was not reported for the loam soil.

FMC Response - The soil adsorption coefficient value was not measured and reported. Soil adsorption coefficients for FMC 54800, however, were measured by FMC for four different soils by both adsorption and desorption processes (Ref. 9). From this study, it can be concluded that the measured values of the soil adsorption coefficients are a linear function of the percent organic matter of the soil. The percent organic matter of the four soils measured ranged from a minimum value of 1.3% to a maximum of 3.1%.

The Princeton Greenhouse soil used in the bifenthrin volatility study had an organic matter content of 1.9%. It was chosen because the sand content was 42%. (This is consistent with EPA Guidelines.)

By plotting the values of the soil adsorption coefficients against the percent organic matter for the four soils in the referenced study, the resulting regression line can be used to estimate the soil adsorption coefficient value, K_d, for the Princeton Greenhouse soil. The plotted K_d values were the average values calculated from the adsorption and the desorption processes. A K_d value for the Princeton Greenhouse soil of 4585 was obtained.

In view of the high soil adsorptive behavior of bifenthrin, it is not surprising that the chemical's volatility from moist soil would be minimal as was observed in the lab volatility experiments conducted.

3. Photodegradation in Water (Guideline #161-2)

Wu, J., "Photodegradation of FMC 54800 in Aqueous Solution", FMC Report No. P-1349, unpublished report prepared by FMC Corporation. Originally submitted August 29, 1986 in support of Bifenthrin Technical (EPA Reg. No. 279-3055). Amended Registration Application/Tolerance Petition; Cottonseed, Milk, Meat (fat and meat by-products). Tolerance Petition No. 6F3453. EPA Accession No. 264642.

A. Agency Concern - A 30% by volume cosolvent (acetonitrile) was used.

FMC Response - Representatives of FMC (D.S. Pincus) and EPA/EAB (C. Fletcher and S. Creegar) met on 6/18/84 to discuss the feasibility of using a co-solvent in excess of 1%. FMC was informed that photochemical studies should be run at the lowest possible co-solvent concentrations but levels as high as 30% would be allowed in order to obtain meaningful data. The arguments presented in that meeting are reiterated below.

Bifenthrin has a water solubility of <0.1 ppb. In order to run a photodegradation study on a meaningful and scientifically valid basis it was necessary to dissolve enough test material (at least 1 ppm) in water not only for accurate detection, but also to have enough material for identification of possible photodegradates.

Although bifenthrin is soluble in many organic solvents, only solvents miscible with water could be considered. Commonly used water miscible solvents are: ethanol, methanol, tetrahydrofuran, and acetonitrile (ACN).

ACN was chosen as a cosolvent in this study because it is an aprotic solvent which minimizes the possibility of hydrolytic degradation of test material. It also has a UV cutoff at around 190 nm. Photodegradation studies require a light source >290 nm; therefore ACN would not interfere with any photolytic processes.

Since it had been determined that acetonitrile would not interfere, it was necessary to determine the level of acetonitrile needed to maintain bifenthrin in solution. Preliminary investigations were done in the Metabolism Laboratories to determine the suitable ratio of ACN to be used in this study. The following experiments were run. One ppm of ^{14}C

bifenthrin was placed in four different flasks and 1%, 10%, 20% and 30% of ACN was added to each flask. Aliquots of 0.1 ml were taken 2-7 days after solutions were made for total ^{14}C recoveries. The radioactivity recovery was not quantitative at lower % ACN levels including 1, 10, and 20%. Recoveries ranged from 19.2 to 83.5% during the 2-7 day exposure period. Vigorous mixing of the samples resulted in a significant increase in radiocarbon recoveries.

This indicates that some of the test material was adsorbed to the glass surface. To determine whether the radioactivity recovered in solution was homogeneous or non-homogeneous, test solutions of 10, 20, and 30% ACN were also centrifuged. Data indicated that most of the radioactivity came out of solution at 10 and 20% ACN solution but not at 30%. When 30% of ACN was used, solution was homogeneous throughout the entire testing period.

Another experiment was designed to determine the possibility of using 1% ACN. The test material was reduced to 0.1 ppm, in order to obtain a uniform and homogeneous test solution. The recoveries of test material were measured before and after solutions were mixed for a 3-day test period. It was obvious that ^{14}C recoveries were not satisfactory before mixing. After mixing, most of the ^{14}C material tended to be uniform.

The data clearly suggested that 1% of ACN COULD NOT maintain bifenthrin in water solution for the entire period of the photodegradation study. Only 30% ACN gave a uniform and homogeneous test solution.

Therefore, 30% ACN and 1 ppm of bifenthrin was selected as optimum test parameters for this study.

B. Agency Concern - Test solutions were not buffered.

FMC Response -Bifenthrin is stable at pH 5-9 (as shown in FMC's hydrolysis study) (Ref. 8). Under the test conditions described in the photodegradation report, the test compound was stable in all of the dark control samples throughout the entire test period indicating no hydrolytic effects. In addition, bifenthrin has low water solubility, thus, if a buffer solution was used, a probable salting-out effect would reduce its water solubility even more. Therefore, the use of a buffer was ruled out as a necessity for the study.

C. Agency Concern - Temperature ranged from 14° to 30°C.

FMC Response - The temperatures of the reported photodegradation study were nominally maintained at 25°C by using a constant temperature water bath throughout the entire study period, both under indoor and outdoor conditions.

For indoor studies, due to a well controlled environment, (including the laboratory) the temperature was almost constant. Therefore, it was possible to maintain the test solutions at 25°C ± 1°. When conducting studies outdoors, efforts were made to keep the temperatures of the test solutions constant. Due to the large fluctuations of outdoor environmental temperature, it was occasionally technically difficult to maintain the test solution at a constant level 25°C. Overall, the average outdoor temperature was in a range approximating 25°C.

D. Agency Concern - Comparisons of artificial light with natural sunlight were illegible.

FMC Response - A legible copy of tabular data comparing natural and artificial light is provided as attached.

In summary, the results of a combined study utilizing both indoor light (artificial light) and outdoor (natural sunlight) conditions adequately demonstrate that solution of bifenthrin can be photochemically altered by certain processes. The processes include cis-trans isomerization, hydrolysis to the acid and alcohol moieties, and to a minor degree, oxidation (hydroxylation) of the intact molecule. Furthermore, the degradation half-life of the process can vary from less than one day to in excess of six months, depending on environmental conditions and the presence of chemicals acting as sensitizers (activators) of the photochemical process.

4. Fish Accumulation (Guideline #165-4)

Tullman, R.H., Analysis of ^{14}C-FMC 54800 ^{14}C Residues in Bluegill Sunfish and Water, Report No. P-1342, March 15, 1986. Unpublished report prepared by FMC Corporation. Unpublished report prepared by FMC Corporation. Originally submitted August 29, 1986 in support of Bifenthrin Technical (EPA Reg. No. 279-3055). Amended Registration Application/Tolerance Petition; Cottonseed, Milk, Meat (fat and meat by-products). Tolerance Petition No. 6F3453. EPA Accession No. 264642.

A. Agency Concern - Fish were not exposed to parent ^{14}C-bifenthrin based on water analysis showing ca 40% of other species.

FMC Response - The chemical to which fish were exposed via proportional diluter was high cis [redacted] bifenthrin. The major product in the fish water other than cis-bifenthrin was the trans-isomer of bifenthrin [redacted]

The highest concentration of bifenthrin achievable was on the order of 19 ppt (parts per trillion) between exposure day 52 and 63. The sample analyzed was a pooled sample containing extracts from two aquaria taken at 0, 14 and 42 days, during which time the average water concentration was 0.9 ppt (parts per trillion). The combination of these extracts was necessary due to the extremely low radioactivity level present. Each extract represented solvent partition of 4L of aquarium water which contained an average of 636 dpm.

The presence of trans-bifenthrin in the analyzed samples arises most likely from photochemical degradation of the extremely dilute solution. The product may also be present as an excreted metabolite of the parent compound (as stated in the report). Laboratory photolysis studies, (See Section 3.D on page 13 of this response), have demonstrated that cis to trans conversion occurs, especially in the presence of organic photosensitizers. The dilute aquarium solution containing diverse organic materials from fish excreta would be a favorable environment for photochemical reactions.

It should be noted that constituents found in analysis of the aquarium water would be expected to reflect excreted metabolites of the parent compound as well as the parent itself. Analysis was done to confirm the identity of the radioactivity as

bifenthrin and/or metabolic products thereof and not to establish the presence of bifenthrin in the dosing solution. Agency guidelines (Subdivision N 165-4) do not specify that analysis of the water for other than total concentration (radiocarbon) is necessary.

Bioconcentration factors on the order of 2000-8700X were observed, and the major identifiable product was cis-bifenthrin.

These data indicate that there is a high bioconcentration of the test compound in fish tissues. Given the worst case scenario in which fish were exposed to a mixture of bifenthrin isomers, the bioconcentration factors for pure cis material might double in magnitude. However, the change from 2000-8700X to 4000-17,400X would not alter the conclusion of the study, i.e., that this compound is subject to high bioconcentration in bluegill sunfish. Repetition of the study under any standard protocol would not be expected to yield significantly different results or lead to different conclusions.

B. Agency Concern - It was not stated as to whether the concentration was 1/10 of the bluegill 96 hour LC_{50}.

FMC Response - There was no fish mortality or other indication of toxicity during the exposure/depuration phases of the test. The reported 96 hour LC_{50} for bifenthrin is 260 ppt (parts per trillion) (Ref. 10). The highest concentration achieved in the bioaccumulation study was 19 ppt or 7.3% of the 96 hour LC_{50}. The extremely low water solubility of bifenthrin necessitated the use of cosolvents in carrying out each experiment. As toxicity to fish is a concern in accumulation experiments of this type, water levels of cosolvent and radiochemical were kept low to avoid toxicity problems.

C. Agency Concern - Untreated fish and water samples were not analyzed.

FMC Response -Untreated water and fish were not analyzed because they were not exposed to any radioactive material. The use of untreated controls in this study was for monitoring possible toxic effects on fish of the cosolvent/vehicle (DMF) used in the study. Fortifications of control samples with the ^{14}C chemical were analyzed, and the recovered radioactivity was completely attributable to that which had been added.

In summary, the studies done to satisfy the Agency requirement for laboratory accumulation in fish of FMC 54800 (Bifenthrin) are scientifically sound and satisfy EPA guidelines by providing information on both the bioaccumulation potential of FMC 54800 in the bluegill sunfish and identification of the major radioactive residues in the tissues of the bluegill. The finding that isomerization of the administered parent compound occurred in the fish water in no way alters the conclusions of the study and accurately represents the fate of this compound in the environment.

5. Aerobic Soil Metabolism (Guideline #162-1)

Bixler, T.A., "FMC 54800 Aerobic Soil Degradation). FMC Report No. P-0712, September 20, 1983. Unpublished report prepared by FMC Corporation. Originally submitted to EPA on November 3, 1983, in support of the Experimental Use Permit No. 279-EUP-101 for FMC 54800 Insecticide. EPA Accession No. 251728 (Ref. 3). See Also Ref. 4, 5, 11, 12 and 13).

A. Agency Concern - Listed as a data gap. No data were reviewed but data are required.

FMC Response - A total of six reports have been submitted to the Agency in support of bifenthrin registration objectives. (See Ref. 3, 4, 5, 11, 12 and 13.)

Soil metabolism data in References 3, 4, 5, and 11 were reviewed by the Agency in response to FMC cotton EUP/Temporary Tolerance Petition. Studies were tentatively considered deficient due to differences in soil half-lives of parent chemical reported for acid-^{14}C FMC 54800 vs. alcohol-^{14}C FMC 54800 as determined by regression analysis. The registrant was requested to provide an adequate explanation for the half-life differences. FMC provided such an explanation in its Environmental Fate (Section H) overview in the Registration Application/Tolerance Petition for bifenthrin on cotton.

The following explanatory items were presented in support of aerobic soil metabolism. For the convenience of the reviewer, FMC's response is reiterated below.

FMC Corporation concludes that the data are adequate for the following reasons:

- Some degree of diversity in data can be attributed to experimental variability. Although experimental conditions were consistent in previously reported studies, work was conducted in different batches of common soil types. Batch to batch variation in soil microbial activity can be expected. Studies were also conducted at different time periods. For example, laboratory efforts reported for alcohol-^{14}C bifenthrin were conducted from 6/83 to 11/83 while efforts related to acid-^{14}C bifenthrin took place from 9/83 to 3/84.

- Application of a kinetic law to a process with a slow rate of change can lead to significant discrepancies in calculation of rate constants and half-lives as the slope of a line tends toward zero. The process can be significantly impacted by experimental variability even with the utilization of statistical (i.e., regression) analysis of resulting data.

For example, calculated rates of decay (-k) for an assumed first-order process yield small rate constants for data reported in References 4 and 11 (0.0004 - 0.007 day^{-1}) (Table 1). Thus small perturbations in data can lead to changes of 0.0001 - 0.002 day^{-1} which although small in absolute terms can cause relatively significant changes in equally diminutive calculated rate constants. It should be noted that the largest discrepancy in calculated half-life was observed in the silt loam soil which exhibited the slowest rate of change.

Thus, in view of the slow degradation rates observed in all cases, and the experimental variability due to conducting experiments at different times with different batches of soil, it is felt that the reported kinetic data represent an accurate profile of the aerobic soil metabolism of bifenthrin.

Table 1

Tabulated Kinetic[1/] Parameters From Soil Metabolism of Alcohol and Acid Labeled FMC 54800

Soil Type	Alcohol Label $t_{1/2}$ (days)	Alcohol Label $-k$[2/]	Alcohol Label R^2	Acid Label $t_{1/2}$ (days)	Acid Label $-k$	Acid Label R^2	Diff (-k)	% Diff (-k)
Silty Clay loam	97	0.0072	0.981	128	0.0054	0.99	0.0018	25
Sandy Loam	116	0.006	0.966	131.7	0.0053	0.774	0.0007	11.7
Silt Loam	155	0.00045	0.980	250	0.00028	0.999	0.00017	37

1/ From first order kinetics analysis (linear regression data)

2/ Units are day^{-1}

Additional chromatographic analyses were conducted on extractable residues isolated from studies on three soil types described in References 3, 4, and 11 in order to confirm the identity of major products. Finally, non-extractable residues from two of the soil types (sandy loam and silty clay loam) were subjected to further extraction and digestion (acid/base) in order to provide additional information on the nature of these products.

In summary, FMC feels it has provided a composite data package which adequately addresses the fate of bifenthrin in soil under aerobic conditions.

6. Soil Dissipation (Guideline #164-1)

Stearns, J.W., "Dissipation of Residues of FMC 54800 in Soils Treated with Capture^{R} 2.0 EC". FMC Report No. RAN-0141, November, 1984. Unpublished report prepared by FMC Corporation. Originally submitted August 29, 1986 in support of Bifenthrin Technical (EPA REg. No. 279-3055). Amended Registration Application/Tolerance Petition; Cottonseed, Milk, Meat (fat and meat by-products). Tolerance Petition No. 6F3453. EPA Accession No. 264642.

Pejovich, R.J., "Determination of Residues of Bifenthrin in Soils Treated with Brigade^{R} 10 WP". FMC Report No. RAN-0166, August, 1985. Unpublished report prepared by FMC Corporation. Originally submitted August 29, 1986 in support of Bifenthrin Technical (EPA Reg. No. 279-3055). Amended Registration Application/Tolerance Petition; Cottonseed, Milk, Meat (fat and meat by-products). Tolerance Petition No. 6F3453. EPA Accession No. 264642.

The following responses refer to both sets of comments from the EAB review.

A. Agency Concern - The formation and decline of parent and its degradates were not addressed.

FMC Response - Bifenthrin residues were analyzed in both studies. The pattern of decline of parent residues has been clearly established. Although the soil samples were not analyzed for the major degradate of bifenthrin (4'-OH-bifenthrin) in study number RAN-0141, soil samples were analyzed for 4'-OH-bifenthrin in study number RAN-0166 and as reported no residues were found. No other metabolites were investigated since based on the soil metabolism studies (Ref. 3, 4, 5, 11, 12, 13, and 14), the only metabolite found was 4'-OH-bifenthrin whose concentration did not exceed 10% of the total residue in any of the studies.

B. Agency Concern - The soil was not sampled deep enough to define the extent of leaching.

FMC Response - As the reviewer stated, residues of bifenthrin were found in the 6-12" layer from several sampling intervals. However, it must be noted that there were residues of bifenthrin in the 6-12" layer at 0 days.

This phenomena could only be caused by contamination by the upper layer during sampling. Logic says that if one contaminates the 0 day sampling interval, one could readily contaminate other sampling intervals. Consequently, we discounted the importance of the low residues found in the 6-12" layers.

In a separate study (Ref. 15), we measured the mobility of bifenthrin in a range of soil types which encompass the soils reported in this study. In all soils, bifenthrin was classified as a low (sand) to immobile (sandy loam, silt loam, silty clay loam) compound. This data further substantiates a lack of bifenthrin mobility in soil.

C. Agency Concern - Field test data, including depth to the water table, test plot dimensions, grade, and soil temperatures, were incomplete.

FMC Response - Field test data including depth to the water table, test plot dimensions and grade are being collected and will be submitted to the Agency as soon as they are received. This information does not affect the scientific validity of the study. Soil temperatures are not required by current EPA guidelines and were not taken.

D. Agency Concern - Storage stability data were not provided. Furthermore, the storage intervals were not reported.

FMC Response - A 2 year soil storage stability study was conducted between June, 1984 and July, 1986 using three soil types (silt loam, sandy loam and sandy clay loam). Samples were stored at -18°C. At the 1 year interval there was only a 4% loss of parent compound. At the 2 year interval, there was less than a 20% loss of parent compound in any soil type. (Ref. 16 and 17).

The longest storage interval for any soil sample was 16 months (zero day samples), well within the time frame of the soil storage stability study.

E. Agency Concern - The test soil from Arkansas was identified as a silt loam but was actually a loam according to the USDA Soil Textural Classification system.

FMC Response - FMC agrees with the Agency's conclusion. The soil from Marion, Arkansas is a loam according to the USDA Soil Textural Classification system.

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F. Agency Concern - Soils were not sampled prior to treatment.

FMC Response - Soil samples were taken from an untreated test plot that was either adjacent to or close to the treated plot. The zero day samples had no detectable residues of bifenthrin (<0.01 ppm).

III. REFERENCES

Ref. No.

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3. Bixler, T.A., "FMC 54800 Aerobic Soil Degradation". FMC Report No. P-0712, September 20, 1983. Unpublished report prepared by FMC Corporation. Originally submitted to EPA on November 3, 1983, in support of the Experimental Use Permit No. 279-EUP-101 for FMC 54800 Insecticide. EPA Accession No. 251728.

4. Bixler, T.A., "Fate of Alcohol (phenyl)-^{14}C FMC 54800 in Soil After 120 Days". FMC Report No. P-0800, January 1, 1984. Unpublished report prepared by FMC Corporation. Originally submitted to EPA on August 15, 1984, in support of Registration Application No. 279-NLA for FMC 54800 use on greenhouse ornamentals, trees and shrubs. EPA Accession No. 254401.

5. Reynolds, J.L., "Aerobic Soil Metabolism of FMC 54800 Degradation During the First 21 Days Following Treatment". FMC Report No. P-1009, November 7, 1984. Unpublished report prepared by FMC Corporation. Originally submitted on DecembeR 20, 1984 in support of EUP/Temporary Tolerance Petition No. 5G3201 for FMC 54800 use on cotton. EPA Accession No. 073174.

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