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OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

MEMORANDUM

SUBJECT: Toxicology Comments on Worker Exposure Study to Support Application for Registration of Biflex Termiticide

TO: Hebert/LaRocca, PM 13  
Registration Division (H7505C)

FROM: Byron T. Backus, Ph.D., Toxicologist  
Toxicology Branch 2  
HED (H7509C)

*Byron T. Backus*  
8/3/92

THROUGH: K. Clark Swentzel  
Section Head, Review Section 2  
Toxicology Branch 2  
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*K. Clark Swentzel* 8/4/92

and

Marcia van Gemert, Ph.D., Branch Chief  
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*Marcia van Gemert* 8/5/92

DP Barcode D173116

Case 016658

Project No. 2-1024

Tox. Chem. 463F

Action Requested:

"A worker exposure study has been sent to OREB for review. We have requested that OREB pass their comments to you upon completion of their review. Please conduct an exposure/risk assessment (from use) since Bifenthrin is a carcinogen."

Additional Relevant Information:

The Health Effects Division Carcinogenicity Peer Review Committee met on January 22, 1992, and agreed that Bifenthrin should be classified as a Group C (possible) human carcinogen, and for the purpose of risk characterization, the Reference Dose (RfD) approach should be used quantification of human risk. The current RfD for Bifenthrin is 0.015 mg/kg/day, equivalent to 15 µg/kg/day.

As of the current date (7/30/92) Toxicology Branch 2 has not received an OREB review of the Biflex worker exposure study. However, Toxicology Branch 2 does have a copy of the study ("Monitoring Exposure to Mixer/Loaders and Applicators to Bifenthrin Insecticide used as a Termiticide Post Construction," study no. A90-3331) as well as a cover letter (dated December 27, 1991) from FMC Corporation.

Comments and Recommendations:

1. According to the cover letter of December 27, 1991 the geometric mean rates of dermal exposure were 0.84 and 1.97  $\mu\text{g}/\text{kg}$  bw/lb A.I. for mixer/loaders and applicators respectively. From the individual data sheets (p. 70-104) individual exposures ranged from 0.141 to 39.556  $\mu\text{g}/\text{kg}/\text{day}$  (mean: 6.561, with a SD of 11.027) for mixer/loaders and 0.565 to 22.683  $\mu\text{g}/\text{kg}/\text{day}$  (mean: 9.599, with a SD of 7.921) for applicators. In a dermal absorption study (Acc. no. 264639) the maximum percentage of Bifenthrin absorbed by the skin was 71.34%; so that the level of dermal exposure associated with absorption of 15  $\mu\text{g}/\text{kg}/\text{day}$  (the RfD) would be obtained by dividing this value by 0.7134, resulting in 21  $\mu\text{g}/\text{kg}/\text{day}$ .
2. For this proposed use the data indicate there is very little exposure to Bifenthrin by inhalation as compared to the dermal route (geometric mean rates of dermal exposure: mixers/loaders: 0.84  $\mu\text{g}/\text{kg}$  bw/lb a.i.; applicators: 1.97  $\mu\text{g}/\text{kg}$  bw/lb a.i.; for inhalation the corresponding values are 0.003 and 0.008  $\mu\text{g}/\text{kg}$  bw/lb a.i. respectively). If OREB can accept these values for inhalation exposure, then Toxicology Branch.2 has no significant concerns regarding the respiratory exposure to Bifenthrin associated with use of this formulation as a termiticide.
3. While a number of the reported daily individual dermal exposures were above 21  $\mu\text{g}/\text{kg}/\text{day}$ , there would presumably be interrelated mitigating factors (working only 5 days a week, not necessarily being exposed to Bifenthrin every working day of the year, the possibility that use of Bifenthrin as a termiticide would be seasonal) that would effectively and substantially lower exposure to Bifenthrin. OREB would have to quantify the "actual" exposure levels, but if OREB concludes dermal exposure means are about 25% or less of the 21  $\mu\text{g}/\text{kg}/\text{day}$  level, then this would still allow a substantive contribution of exposure to Bifenthrin from tolerances on agricultural commodities. Under these circumstances, Toxicology Branch 2 would have no objections to the proposed use of the Biflex formulation as a termiticide.

Individual Data (from p. 70-103):

Mixer/Helpers:

<u>Page #</u>	<u>Total <math>\mu</math>g dermal exposure</u>	<u>Body wt (kg)</u>	<u>Exposure (<math>\mu</math>g/kg)</u>
70	526.2	78	6.746
71	741.0	88	8.420
72	98.6	83	1.188
73	3298.4	111	29.715
74	93.5	82	1.140
75	154.1	76	2.028
76	125.4	80	1.568
77	12.8	91	0.141
78	477.5	80	5.969
79	3204.0	81	39.556
80	624.8	88	7.100
81	248.9	67	3.715
82	72.5	88	0.824
83	21.5	87	0.247
84	83.3	90	0.926
85	113.1	88	1.285
86	82.1	84	0.977
			Mean 6.561
			S.D. 11.027

Applicators

<u>Page #</u>	<u>Total <math>\mu</math>g dermal exposure</u>	<u>Body wt (kg)</u>	<u>Exposure (<math>\mu</math>g/kg)</u>
87	632.4	70	9.034
88	1085.8	83	13.082
89	419.3	108	3.882
90	197.2	82	2.405
91	2036.1	110	18.51
92	1474.4	65	22.683
93	59.6	70	0.851
94	46.3	82	0.565
95	902.5	88	10.256
96	543.5	79	6.880
97	715.1	80	8.939
98	359.6	64	5.619
99	608.4	89	6.836
100	687.8	88	7.816
101	1053.4	86	12.249
102	293.9	84	3.499
103	2495.9	83	30.071
			Mean 9.599
			S.D. 7.921