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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: REVIEW OF BIFENTHRIN EUP FOR TERMITICIDE USE
(HED PROJECTS 1-0321, 1-0774, 1-1057)

TO: George LaRocca, PM 15
Registration Division (H7505C)

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Please find below the OREB review of

HED Project #: 1-0321, 1-0774, 1-1057

RD or SRRD Record #: 162680

Caswell #: 652BB

Date Received: 3/22/91 Review Time: 3 days

Date Returned: 7/10/91

- Deferral to: Biological Analysis Branch/BEAD
- Science Analysis & Coordination Branch
- TB - Insecticide/Rodenticide Support Section
- TB - Herbicide/Fungicide/Antimicrobial Support Section

1.0 INTRODUCTION

FMC Corporation has submitted protocols for mixer/loader, applicator, and indoor air monitoring studies for bifenthrin when used for subterranean termite control. The proposed formulation is an emulsifiable concentrate containing 13 percent active ingredient. The material is to be for sale to and use by professional pest control operators only and would be marketed under the trade name Biflex. The registrant submitted a request for an Experimental Use Permit (EUP) which was addressed by OREB/NDEB in a memorandum dated September 27, 1990 (1) indicating that the limited use of this material as specified in the EUP would not result in unacceptable risk. The registrant has also submitted an air monitoring study for a single house treated with the product. The current submissions contain the results of this limited study and protocols for the air monitoring and worker exposure studies. A meeting was held between OREB, RD, and the registrant on March 26, 1991 to discuss possible amendments to these protocols. These changes are included in the current submissions.

2.0 CONCLUSIONS

The registrant has submitted two study protocols, the results of a pilot air monitoring study, and a proposed label for Biflex TC. These items require only minor changes and clarifications to become acceptable. The individual comments for the two protocols are included in Subsections 4.2 and 5.2 for the air monitoring protocol and worker exposure study, respectively.

3.0 DESCRIPTION AND RESULTS OF PILOT STUDY (MRID No. 417877-01)

Biflex TC termiticide, containing bifenthrin as the active ingredient, was applied to a single home in New Jersey. The home was of a mixed basement/slab construction and was treated by injection through the basement floor or exteriorly by rodding. The product was applied as a nominal 0.62 percent emulsion by a licensed pest control operator. The actual bifenthrin concentrations in the formulation and finished emulsion were 24.4 percent (W/W) and 0.060 percent, respectively. Air was sampled in the basement, kitchen, and master bedroom before application, on the day of treatment, and at intervals of 1, 3, and 7 days after treatment. Air was sampled for 8 hours for both bifenthrin and aromatic components of the formulation. A central air conditioning system was in operation during sampling. Bifenthrin was sampled by drawing air through glass fiber filters at a flow rate of 2 liters per minute using calibrated air sampling pumps. The aromatic components were sampled using charcoal tubes and a flow rate of 0.1 liters per minute.

The bifenthrin samples were extracted with hexane and the active ingredient was analyzed by gas chromatography using an electron

capture detector. The aromatic components on charcoal tubes were desorbed with carbon disulfide and quantified by gas chromatography using a flame ionization detector. The non-detect level for bifenthrin was equivalent to $0.045 \mu\text{g}/\text{m}^3$. Recovery values for laboratory spiked averaged 116 percent (Range: 113-118 at spike levels of $0.41\text{-}1.02 \mu\text{g}$). Samples spiked at a level of $0.1234 \mu\text{g}$ and taken into the field for blind coding averaged 57.6 percent recovery (20-96 percent). It was not clear whether air was drawn through these samples before analysis to determine trapping efficiency and breakthrough. The recoveries of samples spiked with aromatic compounds averaged 110 percent. No bifenthrin was detected in the indoor air of any of the rooms at any of the sampling intervals. Air levels of the aromatic compounds reached 1.02 ppm in the basement on the day after treatment. Average levels in all three rooms were about 0.5 ppm after 3 days and had decreased to 0.12 ppm or less after 7 days.

4.0 AIR MONITORING PROTOCOL

4.1 Description

The registrant proposes to sample indoor air in 15 homes following treatment for subterranean termite control with bifenthrin formulations. The formulation will be Biflex TC which is also known as CAPTURE 2 EC (EPA Registration No. 279-3069). The material was proposed to be applied as a 0.62 percent emulsion. The registrant has indicated that this label rate has been increased and will apply the insecticide at the maximum label rate during this study. The study will address several different construction types as outlined in Table 1. The registrant, in a meeting held on March 26, 1991, explained that many houses are of mixed construction and requested clarification from OREB. OREB requires that these construction types be documented, such as a home with both slab and basement elements, but does not require that a home be of a single construction type. Mixed construction types are acceptable but all construction types should be adequately represented. OREB emphasizes that basement construction is probably a worse case and that plenum construction represents a different, possibly unique, scenario and should be addressed separately. Homes will be located in different geographical areas as reflected in Table 1. Treatments will be performed by licensed pest control operators (PCOs) as a water emulsion at the maximum label rate.

A 500 ml sample of the finished emulsion will be collected for analysis in order to confirm the application rate. Air will be sampled for bifenthrin and aromatic components in the emulsion. Duplicate samples, located near the center of the room at a height of 1 to 5 feet, will be taken from the living areas: basement, kitchen, second floor bedroom, and first floor bedroom if present. Bifenthrin will be collected on glass fiber filters

at a flow rate of 2.0 liters per minute. The aromatic compounds will be collected in charcoal tubes with a sampling rate of 0.1 liters per minute. Sampling duration will be 8 hours for both types of samples. The air conditioning or heating system will be in operation during the sampling. Both the indoor and outdoor temperature will be measured at the sampling site at each interval.

Table 1. Selection of Construction Types for Homes Monitored for Bifenthrin Termiticide.

Number of Homes	Construction Type
3	Basement
3	Slab
3	Crawlspace
3	Plenum
3	Broadcast

4.2 OREB Comments

The registrant has submitted a protocol for a study measuring bifenthrin and aromatic compound concentrations in the indoor air of homes treated with BIFLEX TC for subterranean termite control. The protocol, with a minor few changes and clarifications, would become acceptable. These changes/clarifications have been discussed by telephone with the registrant. OREB notes that in the pilot study the recovery samples spiked and included with the study were highly variable, ranging from 20 to 96 percent. It will be necessary for the registrant to verify the efficiency of the apparatus in trapping and holding the material. This may help explain the variability of the field recovery samples and determine the source of this variability. The registrant stated that air conditioning or heating system will be operational during sampling. The status of other sources of ventilation, such as open windows should also be documented. The registrant proposes to sample 24 hours after application. The registrant should take additional samples at longer intervals, perhaps after 3 and 7 days, and be prepared to take additional samples at longer duration should detectable residues be found in the air.

5.0 MIXER/LOADER APPLICATOR EXPOSURE STUDY

5.1 Description of Study Protocol

Dermal and respiratory exposures of workers will be measured during the mixing/loading and application of the termiticide bifenthrin (BIFLEX TC). Monitoring will be conducted during the

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application of the material to bare soil, representing exposures received during preconstruction treatment. Similar measurements will be taken during treatment of existing structures by rodding and/or trenching as commonly performed during post-construction treatment. Applications will be conducted by 2 person crews; a mixer/loader and an applicator. The mixing/loading and application tasks will be monitored separately. All mixing/loading operations will use open pour techniques. Eight to 10 replicates will be performed for each application method, resulting in a total of 16-20 replicates. At least 15 of these replicates will be uncompromised. Each replicate will consist of the treatment of 1 house or house-sized surface. At least 6 different mixer/loaders and applicators will be monitored. Applications will be made at the label maximum rate. Workers will wear long sleeve shirts, long trousers, socks, and shoes and will follow typical work practices. No attempt will be made to alter the normal work clothing.

Exposures will be normalized by the amount of active ingredient handled. Lot numbers of the formulation will be recorded and samples taken from approximately 20 percent of the containers for analysis. Samples of the finished emulsion from each tankload will also be collected and analyzed. Weather conditions will be recorded.

Dermal exposures will be monitored using whole body dosimeters (union suits) worn beneath the workers' normal clothing. Workers will wear chemical resistant gloves. Exposure of the hands under the protective gloves will be measured by hand rinse or by the use of cotton gloves worn under the protective gloves. Exposures of the "v" of the neck, back of the neck, head will be monitored using dosimeter patches made of the same material as the cotton gloves. Foot exposure will be monitored by anklets made of the same material. Respiratory exposure will be monitored by drawing air through glass fiber filters using calibrated personal sampling pumps. The filters will be located in the workers' breathing zone and the sample flow rate will be approximately 2 liters per minute.

Field control samples and field fortified samples will be prepared and exposed to the environment for the duration of each replicate. One of each medium will be a blank control and 2 of each medium will be spiked with a solution of Biflex TC with a known quantity of hexane. Breakthrough of the insecticide through the glass filters and bag rinse adsorption (if hand washes are used) will be investigated. Target limits of quantification and detection were not included in the protocol but will be developed for each matrix and described in the study report. Analytical methodology was likewise not described in this protocol.

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5.2 OREB Comments

The protocol submitted by the registrant would be acceptable with only minor changes or clarifications. The original protocol specified that hand washes and cotton gloves, one method for each hand, would be used to evaluate hand exposure. OREB discussed this with the registrant in a meeting on March 26, 1991 and it was stated that the registrant should select either of the 2 methods and use that method throughout the study rather than add the confounding variable of monitoring technique to the study. The registrant also states in the protocol that at least 15 of the replicates must be uncompromised. It is OREB's opinion that any replicates removed from the data set also must be reported and that the reasons for deletion of the replicate must be explained.

The protocol states that open pour systems would be used in the study. Page 3 of the proposed label states that Biflex FT (not TC) termiticide should be mixed "using systems that comply with accepted standards that identify a closed-loading system". Either the protocol or the proposed label should be changed so that the study accurately reflects the label requirements. The study protocol also indicates that chemical resistant gloves will be worn during the study. OREB could find no such requirement on the proposed label. Since gloves are commonly worn by termiticide applicators, the label should be amended to require the use of protective gloves. If this change in the label is not made the study design must be altered to eliminate the use of protective gloves.

REFERENCES

- 1) Memorandum from C. Lunchick (NDEB) to D. Liem (TB-II) titled "Applicator and Occupant Exposure to Bifenthrin during Experimental Use as a Termiticide (HED Intra #0049)", dated September 27, 1990.

cc: Correspondence File
D. Jaquith/OREB
Chemical file