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Attached please find the EAB review of:

Reg./File No.: Ac. No. 25 3 748

Chemical: Chlorpyrifos

Type Product: I

Product Name: _____

Company Name: Dow

Submission Purpose: Review protocol for indoor air monitoring

ZBB Code: _____

ACTION CODE: 870

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Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

1.0 INTRODUCTION

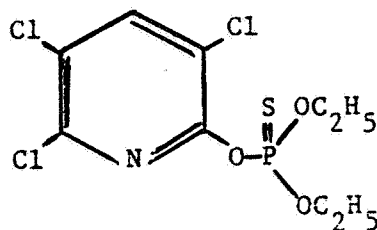
In November 1983, EPA completed a risk/benefit analysis of seven chemicals normally used for subterranean termite control. This review was conducted as a result of an investigation by the General Accounting Office that questioned the adequacy of EPA's regulations which governed the use of pesticides in and around the home.

The risk/benefit information led to the conclusion that benefits derived from the use of termiticides were high, but in order to complete a meaningful risk assessment, additional toxicological and exposure data were required.

A data call-in-notice was sent to termiticide manufacturers at the end of February 1984 which requested that evaluation protocols for the collection of this data be sent to HED/EAB within ninety days. Protocol guidelines for the indoor air monitoring study were included in the request package. These guidelines suggested that the study design contain a mechanism for adequately addressing the effects of air exchange ratio, soil-type, construction-type, temperature, humidity, and HVAC systems on indoor air levels of termiticides. A quality assurance plan was a must, as well as a collection plan for data which would be used to accurately depict the decay rates for termiticide air levels following application according to current label instructions.

In response to the data call-in-notice, Dow Chemical submitted an indoor air monitoring protocol to the Registration division June 6, 1984. The formulation used for this study is DURSBAN TC Termiticide Concentrate (EPA Reg. No. 464-562), an emulsion which contains 42% chlorpyrifos as the active ingredient.

Chlorpyrifos



DURSBAN TC is applied as a 1% emulsion following the aqueous dilution of the packaged concentrate. This working emulsion is then used for pre- or post-construction treatment of the soil around building foundations.

2.0 METHOD

a) Application

DURSBAN TC Termiticide Concentrate will be applied according to current label instructions.

Applicators will be certified PCOs only and adherence to label instructions will be monitored by Dow technical staff.

For the Dow Chemical study, commercial pest control firms will select the homes to be treated. Houses will be furnished and normally occupied during the testing period and a termite treatment history will be obtained from the homeowner.

b) Air Sampling

Air will be pulled through absorber tubes at the rate of one lit/min using battery operated pumps. Each tube will contain two layers of Chromosorb 102 packing adsorbent material. The second layer is to detect sample pull-through. Sampling times will be two hours and this will result in a proposed method sensitivity of 0.08 ug/m³.

Air samples are to be collected for two consecutive days prior to application in order to provide baseline data. Dow's study design calls for samples to be collected at 2,4,8 and 24 hours plus 7,30,90 and 360 days following application. Duplicate samples are to be collected in both the kitchen and bedroom, at a sampling height of four feet. Samples will be collected in the basement for homes which have basement construction. It was proposed that a total of 70 samples be collected for each house studied except for those with basement construction where the total would be 92.

c) Chemical Methodology

Chlorpyrifos residues will be extracted from the chromosorb material and the glass wool plug in front of each section using hexane. The resulting solution will be analyzed using a gas chromatograph with an electron capture detector (Varian 3700) without any sample clean-up.

d) Quality Assurance

Recovery studies are to be conducted by spiking the chemosorb in the absorbent tubes with known amounts of chlorpyrifos and then carrying out the test procedure. For each replicate the chemosorb will be treated with 0.1 to 1 ug of chlorpyrifos

in xylene using a stock solution (0.1 ug/ul) of chlorpyrifos. Duplicate recovery studies will be conducted 2 days before application and again four hours post-application. Known air volumes will be drawn through the field-spike tubes. Chlorpyrifos residues will be extracted and analyzed in the same manner as the test samples.

For each sampling period, one control and one sample blank will be analyzed. The control will be prepared in a similar manner as the recovery samples. The control and blank samples will be analyzed using the same test method.

e) Statistics

It was proposed that standard analysis of variance techniques be used to separate out the effects of construction, season-of-application and status of the heating/cooling system. Non-linear modeling techniques based on a time-weighted average would be used to characterize the decay curve.

f. Reporting Plan

Dow Chemical plans to initiate this air monitoring study in the fall of 1985. An interim report on spring applications should be submitted three months after completion of the 90-day sampling program. The same schedule is to be followed for fall applications. Since data are to be collected for a period of one year, the final report was expected to be submitted in December 1986.

3.0 DISCUSSION

Quality Assurance

The technical reviewers were not sure how Dow Chemical planned to assure the following:

- 1) A uniform application rate for the pesticide formulation would be used in all homes to be tested.
- 2) The same lot of absorbent material would be used for all sample collection to ensure uniformity and trapping efficiency.
- 3) The same analytical laboratory, and technicians would be used to perform sample analyses.
- 4) Check the calibration of the air pumps after sample collection.

- 5) Sealed spike tubes, and sealed sample tubes should be included in the QA plan.
- 6) Xylene was indicated both as a solvent for chlorpyrifos and as an interfering material for the chemical methodology (table 7).

Sampling

EAB's technical reviewers recommend that termiticide manufacturers use 3-consecutive 8-hr sampling periods as this would produce a more representative air sample. This 24-hr sample would encompass different air exchange rates, different types of family activity (absence, play, sleep etc.) hence different breathing rates.

They also believe that the use of dual absorbent layers to be an unnecessary precaution. A good QA plan should provide the best safeguard for detecting sample breakthrough. Up to 100 liters of air can be safely collected this way.

Although the height of the sampling zone was specified, the exact location in the room was not.

Data Collection

It was recommended that three different, detailed data sheets for use by the homeowner, PCO, and Dow's monitoring team be developed to ensure soil-type, treatment history, application rate, and sample collection history.

For example, Dursban has domestic uses other than ground application as a termiticide it is added to cracks and crevices in beams for use as a pesticide. Therefore this type of treatment needs to be identified whenever it occurs as this will effect the test results.

The mass of the absorbent material and sorbent tube should be specified.

CONCLUSIONS

Dow Chemical has submitted a good protocol draft and some changes will make it acceptable. Their study design will allow for the determination of the effect of building construction-type, and season of application on indoor air levels of chlorpyrifos. They have also submitted a good study design for decay-rate determination, and a good draft of a quality assurance plan.

The following protocol modifications are requested:

- 1) The recommended sample size of 32 homes is very small and the proposed number of air samples to be collected per home (70) is high. The number 32 can not be justified on the basis of EAB's statistical review guidelines regarding: 1) Statistical power for detecting significant differences, and 2) Having an acceptable controlled error in estimation.

For example, what is the statistical basis for monitoring 32 homes by collecting 70 samples each as opposed to 320 homes with 7 samples each.

- 2) Decay rate data (0-360 days) need only be collected on 7-12 homes, not 32 as proposed (i.e. one data set in the summer, the other in the winter).
- 3) The effect of air-exchange rate on air levels of chlorpyrifos needs to be adequately addressed in this protocol. This can accurately be assessed by a duplicate experiment in two different homes. This will eliminate the need for off/on HVAC experiments.
- 4) The statistical distribution of their home selection methodology needs to be specified. i.e. 31 plenum, 31 slab in-grade, 31 crawl space etc.
- 5) 10% of all air samples collected must be representative replicates which have to be sent to EPA's Beltsville Laboratory for analysis. These results will serve as an external QA check.
- 6) Air monitoring studies should begin on or about January 1985.



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