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

MAR 9 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 5 (EUP) for Termiticide use of Imidacloprid

FROM: John Tice
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THRU: Mark I. Dow, Ph.D., Section Head
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Health Effects Division (H-7509-C)

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Please find below, the OREB review of:

DP Barcode: D184494

Pesticide Chemical Code: 129099, Imidacloprid

EPA Reg. No.: 003125-EUP-ENU

EPA MRID No.: 425424-01, 425424-02

PHED: NO



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I. INTRODUCTION:

Background/Purpose:

Miles, Inc. has requested an experimental use permit to evaluate efficacy and gather other data on a new, proposed termiticide. The product contains the active ingredient imidacloprid (129099) at a concentration of 21.4% in the product. The final solution concentration will be from 0.01 - 0.1% when applied to the foundations of houses.

Miles prepared two reports to demonstrate "surrogate exposures" in support of their request. These reports are:

- Evaluation of Exposures to Occupants and Professional Pest Control Operators Resulting from PREMISE® 2 TC Use as a Termiticide, MRID 425424-01, September 24, 1992.
- Risk Assessment of PREMISE® 2 TC Used as a Termiticide, MRID 425424-02, October 19, 1992.

Of these reports, This review will only concern the first and evaluate the exposure portion of that report. Toxicology Branch may be interested in the risk assessment document.

II. DETAILED CONSIDERATIONS:

Estimated Occupant Exposure:

Miles used surrogate data which measured air concentrations in 17 houses (of various construction types) treated with Pryfon 6 TC®. To estimate imidacloprid exposures, the concentrations were corrected for the differences in end-use dilution concentration and vapor pressure. The Registrant calculated concentrations range from <0.003 - <0.067 ng/m³. Using the Agency review of the Pryfon 6 TC® data, and using the most conservative numbers during and immediately after application, the Premise® concentrations ranged from 0.003 to 0.095 ng/m³ (nanograms/meter cubed). The highest average concentration in a "living space" came from a house with a crawlspace and from data for the laundry room. The highest concentration in "non-living space" (crawl-space) is estimated as <0.2 ng/m³. Occupant exposures were estimated using these highest concentrations for a living space, 24 hr/day inhalation exposure (doing light work), 70 kg body weight, 1.74 m³/hr respiratory volume (light work-adult male) and 1.02 m³/hr and 30 kg body weight (child). Table 1 contains typical exposures for occupants.

Estimated Applicator Exposure:

Miles submitted surrogate data to support their EUP. Unfortunately, OREB has not seen or reviewed the data. To expedite this action and enable the registrant to gather data necessary for full registration, the applicator exposure data will be accepted as presented. OREB will have the Pryfon 6® surrogate data reviewed for the registration action.

B. TOXICOLOGY CONCERNS

After evaluating a full battery of tests for imidacloprid, Toxicology has determined that there are no acute or chronic concerns about the chemical. Chronic tests are negative for carcinogenicity, acute and developmental tests were not remarkable. The following are the Toxicity Categories for the technical product.

STUDY	TOX CATEGORY
Acute oral-rat	II
Acute dermal	IV
Acute inhalation	IV
Primary eye	IV
Primary Dermal	IV

C. PRIOR EXPOSURE REVIEWS

The first 90 days of the Pryfon 6® air monitoring data have been reviewed and are used to estimate exposures to occupants in treated homes. The review by D. Jaquith dated March 10, 1988 and is located in the Isofenphos (109401) chemical file.

D. Detailed Exposure Calculations

Exposure estimates are based on the highest reported concentration. In using this number, it is recognized that the estimates are conservative.

SEE TABLE 1

TABLE 1

EXPOSURE ESTIMATES FOR PREMISE 2 TC TERMITICIDE

EXPOSED PERSON	PRYFON 6 CONCENTRATION (SURROGATE DATA)	CALCULATED CONCENTRATIONS ¹ (ng/m ³)	BREATHING RATE (m ³ /hr)	DAILY EXPOSURE ²
Adult occupant	0.76 µg/m ³ ³	0.10 ng/m	1.7 m ³ /hr	0.06 ng/kg/day
Child occupant	0.76 µg/m ³	0.10 ng/m	1.02 m ³ /hr	0.08 ng/kg/day

EXPOSED PERSON	UNIT EXPOSURE ⁴	GROSS DAILY EXPOSURE (2.1 lbs)	DAILY EXPOSURE
Adult applicator inhalation	0.002 mg/lb ai	4.2 µg	0.06 µg/kg/day
Adult applicator dermal	0.65 mg/lb ai	1.37 mg	0.02 mg/kg/day

¹ Indoor air concentrations (IAC) for Premise is calculated using the following formula. Initials used are; IAC = Indoor Air Concentration, VP = Vapor Pressure, EUDC = End Use Dilution Concentration.

$$IAC_{PREMISE} (ng/m^3) = IAC_{PRYFON} (\mu g/m^3) \times \frac{1000ng}{1\mu} \times \frac{VP_{imidacloprid}}{VP_{isofenphos}} \times \frac{EUDC_{PREMISE}}{EUDC_{PRYFON}}$$

OR,

$$IAC_{PREMISE} = 0.76 \mu g/m^3 \times \frac{1.5 \times 10^{-9}}{1.6 \times 10^{-6}} \times \frac{0.1\%}{0.75\%} = 0.10 ng/m^3$$

² Daily exposure is calculated using the equation:

$$\frac{Concentration (ng/m^3) * breathing rate (m^3) * 24 hrs}{70 kg bw (30 kg for children)} = Daily exposure (ng/kg/day)$$

³ Air concentration, crawlspace construction, during application.

⁴ Surrogate data for Pest Control Operators (PCO's) applying Pryfon 6. Pryfon 6 and Premise 2 have identical application instructions and should yield similar exposures. The data are not corrected for differences in final dilution concentration.

III. CONCLUSIONS:

OREB estimates that the occupants of a treated dwelling could be exposed to as much as 0.1 nanograms/m³ of imidacloprid in the air immediately after treatment. The air concentrations after 90 days are within the same order of magnitude as they are after treatment. Air concentrations do not appear to decrease rapidly.

PCO exposures are estimated at 0.02 mg/kg/day. These estimates assume that the PCO treats two (2) houses a day and weighs 70 kg.

SURROGATE DATA:

OREB has conditionally accepted the surrogate data presented in MRID 425424-01. While in theory the correction factors for final concentration and vapor pressure are acceptable, confirmatory data that these factors correctly adjust Pryfon 6 data to Premise 2 TC data will be required for full registration. To eliminate the possibility of other properties having a pronounced affect on the indoor concentrations, OREB is requesting additional data. A limited air sampling, in houses of the various construction types, would confirm that the surrogate data adequately estimate indoor air concentrations. The Registrant should feel free to discuss this requirement with OREB.

CC: Correspondence File
Toxicology Branch, I
Imidacloprid File (129099)