MEMORANDUM

DATE: 29-June-99


FROM: Dana Vogel, Chemist Registration Analysis Branch I (RAB1)

TO: Arnold Layne/Mark Dow/Ann Sibold Registration Division (RD)

THRU: Olga Odjott, Biologist RAB1

Melba Morrow, Branch Senior Scientist RAB1

This exposure review was adapted from an assessment previously done by HED/OREB, dated May, 15, 1997(Memo, D.Jaquith, 5/97). Please see the attached exposure assessment for further details. This assessment was amended for an addition of cancer risk calculation and adjustment of the long-term exposure for 1% dermal absorption.

TERMIDOR® 80 WG is a dry powder formulation containing 80 % fipronil as the active ingredient. TERMIDOR® SC is a water soluble liquid concentrate formulation containing 9.1 % fipronil as the active ingredient. Both products are packaged in water soluble paks and are for use by professional pest control operators only. As a minimum, eye protection, chemical resistant gloves, chemical resistant footwear with socks, a long sleeved shirt and long pants or coveralls are recommended. A chemical resistant apron is also recommended when loading, mixing or cleaning equipment. When applying in confined areas a respirator (MSHA/NIOSH approval number TC-21C) must be worn.

Termidor will be applied as a trench, rod, subslab injection or similar subterranean treatment application in or around the foundation and crawl space of the dwelling. The registrant has submitted a report on the vapor pressure of the TGAI. Using the gas saturation method (OECD 1-104), the vapor pressure was found to be 2.8E-09 mm Hg at 25 °C. Therefore, due to the low vapor pressure, and since fipronil will be injected into the dwelling and sealed immediately, HED does not anticipate residential dermal or inhalation exposure to adults or children as a result of the proposed termicide use. The only anticipated exposure will be to the occupational mixer/loader/applicator. In absence of chemical specific data, PHED surrogate data was used to assess worker exposure. Since the proposed use of fipronil applies to commercial pest control applicators, short-, intermediate- and long-term exposures are expected.
Handler Exposure
HED/OREB estimated exposures to pesticide Mixer/Loader/ Applicators using data from PHED V1.1. Application method 16 (Termitecide Injection) was selected from the Mixer/Loader file (MIXLD.FILE), yielding a subset containing 17 records (TERMITICIDE.INJECTION.MLAP). The resulting exposure estimates for mixer/loader/applicators are presented in Table 3 of the attached exposure assessment. This table was derived after normalization by the total amount of material sprayed. Normalization by either the total amount mixed or the average of the amount sprayed and mixed yield slightly different but comparable values.

The registrant submitted data assuming that 200 gallons of a 0.125 percent termiticide emulsion would be applied per day. This is within the range of application volumes recorded in the surrogate studies from PHED and was used by HED/OREB for its calculations. These volumes are presented in Table 4 of the attached memo. The amount handled per day would therefore be:

\[
\text{Lbs ai/day} = 200 \text{ gal} \times 3.785 \text{ l/gal} \times 1.25 \text{ g/l} \times 1 \text{ lb ai/454 g}
\]

\[
= 2.1 \text{ lbs ai/day}
\]

Using this application rate, the average daily dermal and inhalation exposures are calculated to be:

Dermal Exposure (mg/kg/day) = 2.1 lb ai/day x 385 μg/lb ai x 1/70 kg
= 12 μg/kg/day
= 0.012 mg/kg/day

Inhalation Exposure (mg/kg/day) = 2.1 lb ai/day x 2.0 μg/lb ai x 1/70 kg
= 0.060 μg/kg/day
= 0.000060 mg/kg/day

The total daily exposure would be:

Total Daily exposure (mg/kg/day) = 12 μg/kg/day + 0.06 μg/kg/day
= 12 μg/kg/day
= 0.012 mg/kg/day
Table 1 summarizes all exposure estimates for the mixer/loader/applicator of Termidor WG 80.

<table>
<thead>
<tr>
<th>Person Exposed</th>
<th>Exposure (mg/kg/day)</th>
<th>Short- and Intermediate-term MOE</th>
<th>Long-term MOE</th>
<th>Cancer Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixer/Loader/Applicator (single layer, gloves)</td>
<td>1.2 E-02 Dermal</td>
<td>420 Dermal</td>
<td>105</td>
<td>7.3E-07</td>
</tr>
<tr>
<td></td>
<td>6.0E-05 Inhalation</td>
<td>830 Inhalation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 Source: Pesticide Handlers Exposure Database (PHED) V1.1, custom run. PHED Unit exposures (dermal + inhalation) are HIGH Confidence Data.
2 Exposure = Unit exposure(ug/lb ai) x Lbs ai/Day x 1/BW (70kg) x % Absorption (100%-inhalation; 1%-dermal-long-term only)
3 MOE = NOAEL/Exposure; where NOAEL = 5 mg/kg/day for dermal and 0.05 mg/kg/day for inhalation
4 MOE = NOAEL/Combined Exposure(dermal + inhalation); where NOAEL = 0.019 mg/kg/day for dermal and inhalation (1% dermal absorption assumed)
5 Cancer Risk = (Exposure (inhalation + dermal) x 220 days(based on a handler working 5 days per week with 2 weeks vacation per year)/365 days x 35 years/70 year lifetime) x RIF (0.0002 mg/kg/day)

The margins of exposure (MOEs) are 105 and greater for all handling activities. Therefore, since HED's level of concern for fipronil is for MOEs less than 100, exposure to handlers is below the level of concern. The cancer risk was calculated to be 7.3E-07, below HED's level of concern (generally 1E-04 for occupational exposures).

Incident Reports
There are no reported incidents from human exposure to fipronil.

cc: OREB file 129121, D. Vogel (RAB1), Olga Odiott (RAB1).
D. Vogel: 804F:CM#2:(703)305-0874:7509C:RAB1
ATTACHMENT 1
D228384

MEMORANDUM

SUBJECT: EXPOSURE ASSESSMENT FOR FIPRONIL TERMITICIDE

FROM: David Jaquith
Special Review and Registration Section I
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

TO: Michael Metzger, Chief
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

THRU: Jeff Evans, Acting Section Head
Special Review and Registration Section I
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Ed Zager, Acting Chief
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Please find below the OREB review of ....

DP Barcode: _D228384_ Pesticide Chemical Code: _129121_

EPA Reg. No.: _264-XXX_

Deferral to:

PHED: Version 1.1
1.0 INTRODUCTION

OREB has been requested to evaluate an exposure and risk assessment submitted by Rhone Poulenc in support of registration of their termiticide product TERMIDOR® 80 WG. TERMIDOR® 80 WG is a dry powder formulation containing 80 percent Fipronil [-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-((1,R,S)-trifluoromethyl)sulfinyl-1-H-pyrazole-3-carbonitrile] as the active ingredient. The product is packaged in water soluble bags and is for use by professional pest control operators only. As a minimum, eye protection, chemical resistant gloves, chemical resistant footwear with socks, a long sleeved shirt and long pants or coveralls are recommended. A chemical resistant apron is recommended when loading, mixing or cleaning equipment. When applying in confined areas a respirator (MSHA/NIOSH approval number TC-21C) must be worn.

2.0 CONCLUSIONS

OREB has estimated exposures of workers and residents to Fipronil when used as a termiticide. The daily dermal exposures of mixer/loader/applicators was estimated to be 17 µg/kg/day. Both the registrant and OREB derived exposure estimates using PHED V1.1. The subset used addressed the dermal and respiratory exposures of Mixer/Loader/Applicators of termiticides while wearing long sleeved shirts, long pants, and protective gloves. The registrant attempted to refine the estimates from PHED to account for water soluble bag packaging by subtracting exposures when water soluble bags are used for mixing/loading, taken from the Mixer/Loader file from PHED and to adjust for the presence of protective coveralls and chemical resistant aprons (recommended by not REQUIRED by the proposed label) by applying a 90 percent protection factor to areas covered by these garments. It is OREBs opinion that there are insufficient high quality data with which to make these adjustments and that extensive adjustment of the 17 replicates addressing termiticide application would yield a greater error than using unadjusted data that does not quite match the mixing/loading scenario. The data set used to adjust the termiticide mixing/loading/application exposure estimates is rather small and contains several incomplete replicates. The data set selected for termiticide exposure estimation, although limited to 17 replicates from 2 studies, is of uniformly high quality and all body areas are represented in each replicate. The resulting unit exposure estimates were 385 µg/lb ai and 2.0 µg/lb ai for the dermal and respiratory routes, respectively.

The registrant attempted to estimate post-application exposures of the residents of treated homes using surrogate data from studies obtained from the scientific literature. OREB does not
accept surrogate data when the physicochemical properties of the materials are different and can appreciably affect exposure. Fipronil has a much lower vapor pressure than the chemicals referenced by the registrant (chlorpyrifos and chlordane). In lieu of compound-specific data, OREB used a conservative approach and assumed that the air was saturated with Fipronil. Air concentrations of Fipronil vapor were calculated using the Ideal Gas Law. Obviously, this situation can not occur in a household environment and estimates based on this assumption are highly conservative.

The Toxicology Endpoint Selection Document (TES) contains several NOEL values for Fipronil (1). These are listed, along with the resulting Margins of Exposure (MOEs) in Table 1.

<table>
<thead>
<tr>
<th>Person Exposed</th>
<th>NOEL mg/kg/day</th>
<th>Study Type</th>
<th>Exposure mg/kg/day</th>
<th>MOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixer/Loader/Applicator</td>
<td>0.5</td>
<td>Acute Neurotoxicity</td>
<td>1.7 x 10⁻⁴</td>
<td>2.9 x 10³</td>
</tr>
<tr>
<td>(Long sleeves, Long Pants, Gloves)</td>
<td></td>
<td>(gavage)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5.0</td>
<td>21-day Dermal</td>
<td>1.7 x 10⁻⁴</td>
<td>2.9 x 10⁴</td>
</tr>
<tr>
<td>Resident Post-Application - Adult</td>
<td>0.019</td>
<td>2-year Feeding</td>
<td>1.9 x 10⁻⁵</td>
<td>1.0 x 10³</td>
</tr>
<tr>
<td>Resident Post-Application - Child</td>
<td>0.019</td>
<td>2-year Feeding</td>
<td>2.2 x 10⁻⁵</td>
<td>8.6 x 10²</td>
</tr>
</tbody>
</table>

3.0 DETAILED CONSIDERATIONS

3.1 Registrant Calculations - Applicator Exposure

The registrant has submitted an exposure assessment derived from the Pesticide Handlers Exposure Database (PHED), Version 1.1. The registrant selected 17 replicates from the Mixer/Loader/Applicator file (MLAP.FILE) with quality grades of A or B for respiratory, dermal, and hand measurements. These data measured exposures during the mixing/loading and application of
termicidues when an open pouring system was used for the mixer/loader function.

The registrant calculated unit exposures of 2.35, 57.4 and 109.7 μg/lb ai handled. These values were derived from the unit exposure per lb ai sprayed and were adjusted for 90 percent protection from coveralls worn over long sleeved shirt and long pants. The use of protective coveralls is recommended but not required by the proposed label. The registrant then attempted to separate the mixing/loading and application functions and adjust for water soluble bags by subtracting the estimated value obtained from the water soluble bag subset from the Mixer/Loader file (MIXLD.FILE).

3.2 OREB Calculations - Applicator Exposure

OREB also estimated exposures to pesticide Mixer/Loader/Applicators using data from PHED V1.1. Application method 16 (Termiticide Injection) was selected from the Mixer/Loader file (MIXLD.FILE), yielding a subset containing 17 records (TERMITICIDE.INJECTION.MLAP). Examining a Browse/Print of this subset, which is presented in Table 2, indicated that all replicates contained data of either A or B grade for respiratory, dermal, and hand exposure measurements. It was therefore unnecessary to produce more than one set of calculations for this subset. Note that this is NOT often the case with PHED analyses and more often multiple sets of calculations must be performed.

The resulting exposure estimates for mixer/loader/ applicators are presented in Table 3. This table was derived after normalization by the total amount of material sprayed. Normalization by either the total amount mixed or the average of the amount sprayed and mixed yield slightly different but comparable values.

The registrant then adjusted the values presented in Table 3 to account for the protective effects of coveralls, assumed to be 90 percent protection. The label recommends, but DOES NOT REQUIRE, coveralls during mixing/loading and application and a chemical resistant apron during mixing/loading. Adjustment for garments that are not REQUIRED on the label would be inappropriate. Additionally, due to the design of the studies used to derive the exposure estimates, there is no way to adjust for the effectiveness of a protective apron since the exposures during the mixing/loading and application functions were not measured separately. OREB therefore based its exposure estimates on the data without adjustment for additional protective clothing.

The registrant further tried to adjust the mixer/loader/applicator exposures to account for the use of water soluble bags
rather than open pouring. The registrant then tried to replace the mixer/loader portion of the total exposure with limited data reflecting exposures when water soluble bags were used and by including a correction factor for protective coveralls. It is OREB's belief that incorporation of all of these adjustments would yield a data set of lower quality than that obtained from the termiticide mixer/loader/applicator studies specific to termiticide application. OREB realizes that failure to adjust for water soluble bags, this may overestimate the mixing/loading portion of the exposure to some extent and provides a slightly conservative estimate of exposure but will probably have minimal effect on the overall risk associated with this use. A more accurate assessment would more likely result when extensive correction factors and adjustments are not made to the data. In order to further refine the exposure estimates for these individuals, additional data would be needed.

The registrant assumed that 200 gallons of a 0.125 percent termiticide emulsion would be applied per day. This is within the range of application volumes recorded in the surrogate studies from PHED and was used by OREB for its calculations. These volumes are presented in Table 4. The amount handled per day would therefore be:

\[ \text{Lb ai/day} = 200 \text{ gal} \times 3.785 \text{ l/gal} \times 1.25 \text{ g/l} \times 1 \text{ lb ai/454 g} \]

\[ = 2.1 \text{ lb ai/day} \]

The registrant applied a dermal absorption factor of 3 percent. The Toxicology Endpoint Selection Document (TES) indicates that there are no dermal absorption data for this compound and that no correction for dermal absorption should be included (1). The NOEL used for risk assessment was based on a 21-day dermal study for mixer/loader/applicators. Therefore OREB did not apply a correction factor for dermal absorption but has separated out the dermal and respiratory exposure estimates to facilitate recalculation should such information become available. The total potential dermal exposure of a 70 kg worker from Table 3 would be:

\[ \text{Dermal Exp. (mg/kg/day)} = 2.1 \text{ lb ai/day} \times 385 \mu g/lb ai \times 1/70 \text{ kg} \]

\[ = 17 \mu g/kg/day \]

The respiratory exposure would be:

\[ \text{Resp. Exp. (mg/kg/day)} = 2.1 \text{ lb ai/day} \times 2.0 \mu g/lb ai \times 1/70 \text{ kg} \]

\[ = 0.060 \mu g/kg/day \]
The total daily exposure would be:

Total Daily exposure (mg/kg/day) = 17 μg/kg/day + 0.06 μg/kg/day
                                           = 17 μg/kg/day
                                           = 0.017 mg/kg/day

3.3 Registrant Assessment - Residential Post-Application Exposure

There are no data measuring the air concentrations of Fipronil following its use as a termicide. In lieu of such information, the registrant submitted summaries of 4 surrogate studies found in the scientific literature (2,3,4,5).

The registrant then adjusted values for chlorpyrifos to estimate the rate of loss of Fipronil from surfaces using a study from the scientific literature (6). This study determined that the rate of evaporation of pesticides from surfaces was inversely proportional to the vapor pressure multiplied by square root of the molecular weight of the compound. The registrant derived an air concentration of $1.9 \times 10^{-4}$ μg/m$^3$. Using a daily respiratory volume of 20 m$^3$ per day (7) this yields a daily respiratory exposure to a 70 kg individual of $5.4 \times 10^{-5}$ μg/kg/day. The registrant assumed that a 10.2 kg child spends 8 hours of active play with a respiratory volume of 4.2 liters per minute (0.25 m$^3$/hr) and 16 hours at rest with a volume of 1.5 liters per minute (0.09 m$^3$/hr) (7). The daily respiratory volume is therefore:

Resp. Vol. m$^3$/day = [(8 hrs x 0.25 m$^3$/hr) + (16 hrs x 0.09 m$^3$/hr)]
                                           = 3.44 m$^3$/day

This yields a corresponding exposure of $6.5 \times 10^{-5}$ μg/kg/day.

3.4 OREB Assessment - Residential Post-Application Exposure

OREB used a simpler model to estimate post-application respiratory exposure of residents to Fipronil. In lieu of actual measurements, OREB assumed that the atmosphere was saturated with
Fipronil vapor. Using the Ideal Gas Law and a vapor pressure of 2.8 x 10^-9 mm Hg (8), the saturation concentration is:

\[ PV = (g/M)RT; \ g/V = (PM)/(RT) \]

where:
- \( P \) = vapor pressure in atm; 2.8 x 10^-9 mm Hg/760 mm Hg/atm
- \( R \) = Universal Gas Constant = 0.0821 l atm/mol °K
- \( T \) = temperature, °K = 298
- \( V \) = 1 liter
- \( g \) = grams of Fipronil
- \( M \) = molecular weight of Fipronil = 437 g/mol

\[ g/l = MP/RT = \frac{437 \text{ g/mol} \times 3.7 \times 10^{-12} \text{ atm}}{0.0821 \text{ l atm/mol}°\text{K} \times 298} \]

\[ = 6.6 \times 10^{-11} \text{ g/l} = 6.6 \times 10^{-5} \mu g/l \]

\[ = 0.066 \mu g/m^3 \]

The resulting respiratory exposure of a 70 kg adult would be:

Exposure (\( \mu g/kg/day \)) = 0.066 \( \mu g/m^3 \) \times 20 m^3/day \times 1/70 kg

\[ = 0.019 \mu g/kg/day = 1.9 \times 10^{-5} \text{ mg/kg/day} \]

For a 10.2 kg child the corresponding exposure would be:

Exposure (\( \mu g/kg/day \)) = 0.066 \( \mu g/m^3 \) \times 3.44 m^3/day \times 1/10.2 kg

\[ = 0.022 \mu g/kg/day = 2.2 \times 10^{-5} \text{ mg/kg/day} \]

OREB emphasizes that this is a highly conservative estimate and that saturation of the atmosphere with Fipronil will not actually occur. Actual air concentrations are likely to be much less than 0.066 \( \mu g/m^3 \).
Table 2. Browse/Print of Quality Grades for the Subset TERMITICIDE.INJECTION.MLAP from PHED MLAP.FILE.

Sorted by WORKER.ID (A) < TERMITICIDE.INJECTION.MLAP >> (H)

<table>
<thead>
<tr>
<th>Record I.D.</th>
<th>Study Worker Code</th>
<th>Worker ID No.</th>
<th>Airborne Grade</th>
<th>Dermal Uncovered Grade</th>
<th>Dermal Covered Grade</th>
<th>Hand Grade</th>
<th>Meth Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>0512<em>A</em>01</td>
<td>512</td>
<td>A</td>
<td>A</td>
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<tr>
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<td>A</td>
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<td>A</td>
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</tbody>
</table>
Table 3. Estimated Exposures of Mixer/Loader/Applicators Treating Structures with Termicidies Using Injection Methods and Open Pour Mixing/Loading. Workers are assumed to wear long sleeved shirts, long pants and protective gloves. Normalization of Exposures is by amount of active ingredient sprayed.

<table>
<thead>
<tr>
<th>LOCATION</th>
<th>DISTRIB.</th>
<th>MEDIAN</th>
<th>MEAN</th>
<th>Coef of Var</th>
<th>Geo. Mean</th>
<th>Obs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEAD (ALL)</td>
<td>Lognormal</td>
<td>17.29</td>
<td>85.0124</td>
<td>176.6765</td>
<td>17.4233</td>
<td>17</td>
</tr>
<tr>
<td>NECK.FRONT</td>
<td>Lognormal</td>
<td>11.055</td>
<td>317.9744</td>
<td>313.3727</td>
<td>15.0876</td>
<td>17</td>
</tr>
<tr>
<td>NECK.BACK</td>
<td>Lognormal</td>
<td>.671</td>
<td>1.8085</td>
<td>165.5792</td>
<td>.67</td>
<td>17</td>
</tr>
<tr>
<td>UPPER ARMS</td>
<td>Lognormal</td>
<td>6.984</td>
<td>10.4246</td>
<td>95.5097</td>
<td>6.0796</td>
<td>17</td>
</tr>
<tr>
<td>CHEST</td>
<td>Lognormal</td>
<td>7.1</td>
<td>14.3879</td>
<td>105.1891</td>
<td>8.2956</td>
<td>17</td>
</tr>
<tr>
<td>BACK</td>
<td>Lognormal</td>
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<td>7.9562</td>
<td>102.5527</td>
<td>4.6774</td>
<td>17</td>
</tr>
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<td>FOREARMS</td>
<td>Lognormal</td>
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<td>17.5806</td>
<td>96.7333</td>
<td>10.4071</td>
<td>17</td>
</tr>
<tr>
<td>THIGHS</td>
<td>Lognormal</td>
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<td>807.0087</td>
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<td>174.1091</td>
<td>17</td>
</tr>
<tr>
<td>LOWER LEGS</td>
<td>Lognormal</td>
<td>54.264</td>
<td>58.17</td>
<td>83.8473</td>
<td>38.8089</td>
<td>17</td>
</tr>
<tr>
<td>FEET</td>
<td>Lognormal</td>
<td>127.619</td>
<td>297.2269</td>
<td>126.4601</td>
<td>109.7482</td>
<td>17</td>
</tr>
</tbody>
</table>

TOTAL DERM: 385.3068
INHALATION: 1.9688
COMBINED: 387.3331

95% C.I. on Mean: Dermal: [-25517.9624, 28753.0628]
95% C.I. on Geo. Mean: Inhalation: [.4364, 9.4091]
Inhalation Rate: 25 Liters/Minute
Number of Records: 17

Data File: MIXER/LOADER/APPLICATOR
Subset Name: TERMITICIDE.INJECTION.MLAP

Subset Specifications for TERMITICIDE.INJECTION.MLAP

With Application Method Equal to 16 (Termicide Injection)
Subset originated from MLAP.FILE
Table 4. Amounts of Termiticide Mixed and Applied During Studies Submitted to PHED V1.1.

<table>
<thead>
<tr>
<th>Record</th>
<th>Crop Type</th>
<th>Total US Gal Mixed</th>
<th>Total US Gal Sprayed</th>
<th>Total AI Mixed (lb)</th>
<th>Total AI Applied (lb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0512<em>A</em>01</td>
<td>SLAB FOUNDATION, TERMITES</td>
<td>200.0000</td>
<td>150.0000</td>
<td>12.5000</td>
<td>9.0000</td>
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<tr>
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REFERENCES

1) Toxicology Endpoint Selection Document for Fipronil


cc: Fipronil File (129121)
Correspondence file
R. Keigwin (RD/7505C)
D. Jaquith (OREB/7509C)