

PRODUCT PERFORMANCE EVALUATION

by Kevin J. Sweeney, Entomologist - IB

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To: Ann Sibold

Date: October 14, 2004

EPA Reg. or File No.: 7969-209 & 210

Product Name: Termidor SC & Termidor 80WG

Registrant: BASF

PM: Richard Gebken, Acting PM 10

PRIA Action? : yes, non-fast-track

Dec No(s). 341557; 341558

DP: 300987; 300988; 306066; 306067; 305031;

Chemical: fipronil applied at 0.06%, 0.09% and 0.0125%.

Use pattern: insecticide for termite and ant control.

Sites: Residential and commercial structures.

Pests: subterranean and drywood termites, carpenter ant, Argentine ant, big-headed ant, odorous house ant and pavement ant.

Registration Action:

BASF wishes to amend the Termidor SC and Termidor 80WG labels to include a "Exterior Perimeter/Localized Interior Treatment Use Pattern" for control of post-construction subterranean termite infestations. This use pattern requires a mandatory exterior perimeter soil applied treatment combined with spot (localized) interior applications. BASF also requested the creation of a "Master Label" instead of having just one comprehensive label for each of their termiticide products.

ASPCRO comments to the BASF amendments and supporting data:

Detailed ASPCRO comments are attached together with the BASF response to those comments.

1a. ASPCRO requested that the exterior treatment be mandatory ("must"). In contrast to the BASF amendment, ASPCRO insists that the exterior treatment be made in accordance with PR Notice 96-7 and currently accepted termiticide treatment practices, that is, 4 gallons per 10 linear feet per foot of depth up to four feet deep or to the top of the footer.

1b. BASF requests the depth be limited to just two feet of to the top of the footer.

2a. ASPCRO believes that the interior localized treatments should be mandatory and that they "must" be done according to the label.

2b. BASF disagrees citing the success of exterior only treatments.

3a. ASPCRO wants EPA to require a quarterly re-inspection interval following the application of a perimeter only treatment.

3b. BASF disagrees and cites the success of their products based on the EUP data, USDA-FS testing, and the fact that all other registered termiticides do not have any re-inspection interval on their label unless there is an end-use dilution on the label that did not meet OPPTS 810.3600 guideline standards. Under such conditions, a yearly re-inspection is recommended as described in PR Notice 96-7.

BASF also cites current state contractual requirements for termite control applications.

4. ASPCRO did not formally comment on the proposal for a Master Label. However, the membership of ASPCRO did not support this type of labeling for termiticide products when polled at their annual meeting in Williamsburg, VA.

Submitted data:

The data submitted was generated in response to EPA's request that BASF show (under a EUP program) that the subject products perform successfully when applied according to label directions. In addition, EPA requested soil residue data and evidence of fipronil transfer between termites (Transfer Effect).

Admin Material: Termidor 80 WG and Termidor SC Termiticide/Insecticide, EPA Reg. No. 7969-209 and 7969-210, Amended Registration Request-Submission of Supplemental Label with Alternative Use Directions and Supporting Data.

MRID 46215101 Final Report: Overview of Laboratory and Field Research Trials Supporting the Proposed Exterior Perimeter/Localized Interior Treatment (EP/LIT) Use Directions for

Termidor Brand Fipronil by Daniel O'Byrne. January 9, 2004.

MRID 46215102 Summary of Research Articles, Reports and Studies that Document Transfer of Fipronil Between Termites by Mark Coffelt and Robert Davis. January 6, 2004.

MRID 46215103 Soil Residual Behavior of Fipronil Following a Perimeter Application of Termidor Termiticide (Year 2 update of Soil Residue Study USA 01K25) by Jeffery Holmsen. January 9, 2004.

MRID 46215104 Summary of Filed Research Trials Conducted to Evaluate Control of Termites when Termidor Brand Fipronil is Applied as Either an Exterior Perimeter only or Exterior Perimeter/Localized Interior Treatment by Mark Coffelt. January 9, 2004.

Data previously submitted in support of these products and cited by EPA in this review.

MRID 45835604 Interim Report – Soil Residual Behavior of Fipronil Following A Perimeter Application of Termidor Termiticide by Kenn Essig 2002.

I also attached copies of the USDA-Forest Service Reports to the review for the product files. These reports are considered **confidential business information** and should be released only with the permission of BASF.

I summarized the information necessary for a registration decision below:

Table 1. Efficacy of BASF Post-Construction Termidor Applications in support of EP/LIT (# homes tested; % success). Homes that required retreatment 3 Months following the initial treatment were considered a failure. (Retreatments were successful.)

Testing Time/Third Party Study					
	2 years - Silverton Study EUP	2 years- Orkin study	2 years - K03 study EUP	5 years K03 EUP	6 years K03 EUP
Termite sp.	DST	EST FST	EST (80%) DST (1%) FST (19%)		
Exterior only	n=67/78%	n=108/?	n=81/93%	n=10/100%	n=1/100%
EP/LIT	0	0	0	0	0
Conventional	0	0	0	0	0

Comments		Data unacceptable due to poor monitoring			

BASF conducted the K21 study EUP n= 239 homes in 21 states

	1 years -K21 EUP	2 years- K21 EUP			
Termite sp.	EST - 66% (158) DST 22% (52) FST 12% (29)	EST - 66% (158) DST 22% (52) FST 12% (29)			
Exterior only	222/95%	n=113/91%			
EP/LIT		n=17/100%			
Conventional	0	0			
Comments	10 homes failed with exterior treatment only. All received an LIT to control the infestation at 3-12 MAT.	A lot of the homes not receiving the 24 month inspection were in Arizona infested with DST .			

Table 2. Waite and Gold Study - Four of the failures in Table 1a were from this study.

The results of this Master Thesis project is described below because it compared EP only to EP/LIT at all label rates. All homes were infested with termites and all were monitored for 24 MAT. Failure = termite infestation 6 MAT. The four homes that failed in the study were 0.06% EP treated homes with interior termite infestations.

	0.06% EP	0.06% EP/LIT	0.125% EP		
Termites	EST	EST	EST		
#structures n=32	n=11 65%	n=10 100%	n=11 100%		

Tables 3a and 3b. Results of USDA Forest Service Termiticide Testing with all EPA Registered and BASF Experimental Fipronil Formulations.

Table 3a. USDA Forest Service Data Concrete Slab Test Data Stated as Years/%Success

Product/Dilution	Termidor SC	Termidor 80WG (WDG)	Termidor MEM (EC)	Termidor MEC
0.005%	N/A	n/a	n/a	5 yrs/100% 5yrs/80% MS
0.01%	4 years/100%	n/a	n/a	5 yrs/100% 5 yrs/90% MS
0.03%	4 years/100%	7yrs/90%	7 yrs/100%	5 yrs/90%
0.06%	4 years/100%	9yrs/100%	7yrs/90%	5 yrs/100%
0.125%	4 years/100%	9yrs/100%	8 yrs/100%	5 yrs./100%
0.25%	4 years/100%	9 yrs/100%	8 yrs /100%	5yrs/100%
0.5%	n/a	9 yrs/100%	8 yrs/100%	n/a
1.0%	n/a	9yrs/100%	8 yrs/100%	n/a

Table 3b. USDA - Forest Service Data Ground Board Test Data Stated as Years/%Success

Product/Dilution	Termidor SC	Termidor 80WG (WDG)	Termidor MEM	Termidor MEC
0.005%	n/a	n/a	n/a	5 yrs/100% AZ, MS 5 yrs/70% SC 5 yrs/50% FL
0.01%	n/a	n/a	n/a	5yrs 100% AZ, SC 5 yrs/90% MS, FL
0.03%	4 yrs/100% 4 yrs/90%	n/a	n/a	5 yr/100% AZ 5yrs/90% SC,MS,FL
0.06%	4 yrs./100%	7 yrs/100%	7 yrs/100%	5 yrs/100% 5 yrs/90% FL
0.125%	4yrs/100%	7 yrs/100%	8 yrs./100%	5 yrs/100% 5 yrs/90% SC
0.25%	4 yrs./100% 4yrs/90% AZ	9yrs./100%	8yrs./100%	5yrs/100%
0.5%	n/a	9yrs/100%	8 yrs./100%	n/a
1.0%	n/a	9yrs/100%	8yrs/100%	n/a

Table 4. Toxicity of Fipronil Expressed as LC₁₀₀ and LC₅₀ (ppm) to Termite Workers and Soldiers (Note: fiprole metabolites are about as toxic or more toxic)

Termite Species	Waite & Gold	Obrahim et.al	BASF
EST	LC ₁₀₀ 1.0-3.0 and LC ₅₀ 0.26-0.60	No data	LC ₅₀ 0.01ppm LC ₉₀ 0.61 – 0.65 (Morris)
DST	No data	No data	LC ₉₀ = 0.23 – 0.59
FST	No data	LD ₅₀ 1.39 worker LD ₅₀ 1.89 soldier	No data

Table 5. Soil Residue Levels and Longevity in Soil pH 4.9 to 8.2

The BASF study was an open field trench treatment of 0.06% Termidor SC.

No rodding performed in BASF study. Applied at 4gallons/10 linear feet to the trench

The Waite and Gold study was a residential trench and rod treatment of 0.06% Termidor SC

Soil Residue ppm	Waite and Gold 18 months PT fipronil only	BASF 24 months (fiproles)	BASF 24 months (fipronil)
Fipronil/fiproles	19 to 97 ppm Avg = 64 ppm	AVG = 27.9 for all plots in U.S. Arizona = 16.6 Florida = 36.4 (1 year) California = 48.6 NC Clay = 19.4 NC Sand = 27.0	Avg = 22.0 for all U.S. plots Arizona = 12.2 Florida = 27.8 for year 1) California = 39.1 NC clay = 14.3 NC sand = 22.2

Table 6

Fipronil/fiprole soil residues from USDA-FS Concrete Slab and Ground Board Plots

MRID 45835604 Applied 1 gallon or less/rep of WG or the MEM (microemulsion) formulations

Location	Dilution	Ground Board	Concrete Slab
Florida	0.06%	8.51 ppm (4years)	6.69 ppm (5 years)
Arizona	0.06%	1.35 ppm (4 years)	2.25 ppm (5 yrs with WG formulation)
South Carolina	n/a	n/a	n/a
Mississippi	n/a	n/a	n/a

Table 7

Fipronil/fiprole residues from EUP house treatments (MRID 45835604).

Termidor 80WG applied according to the label dilution of 0.06% at 4 gallons/10 linear feet. Soil samples were taken at 50 months post-treatment.

Location	Dilution	Fipronil	Fiprole degradates	
South Carolina	0.06%	7.74 ppm	10.90 ppm	

Table 8. Degradation Model Based on Soil Residue Data Results. These data were also supported by Aventis CropScience data from soil degradation trials after in-furrow and soil surface fipronil applications. The data and model yield a half-life value of eight months in soil for sub-concrete slab applications and five months for exposed soil surface applications. These half-life values are for combined for active fiproles (fipronil, MB46136, and MB 45950). After five years, approximately 0.1 ppm – 0.35 ppm would be expected to be present in exposed soil treated at the 0.6% dilution at 4 gallons/10 linear feet per foot of depth with Termidor 80WG. However, the collected soil residue data submitted to support this termiticide amendment for EP/LIT resulted in much higher than expected residues in nearly all cases. These residue data were collected by at least three different laboratories.

Entomologist's Comment: Based on the toxicity of fipronil to termites, the soil residues present in the exterior and sub-slab soils should be sufficient to kill termites foraging in these soils for at least five years.

Table 9. "Horizontal Transfer" from one termite to another within the same population.

Transfer studies have been performed and published by various authors.

1. Aventis (BASF) performed radiolabelled studies in the laboratory to show that fipronil was transferred from one worker termite to another in the genus *Reticulitermes*. Explained these results based on contact and trophallaxy. Sand was treated at 0.01 ppm fipronil. Fed at 3ppm
2. Ibrahim et al. published a study with Formosan termites in JEE. Significant transfer from soldiers to workers and from worker to worker occurred. However, worker transfer occurred at a high ratio of 1 treated:1 untreated worker.
3. Henderson - at the International Urban Pest Conference - reported that fipronil works more slowly than imidacloprid. As a result, more transfer can occur.
4. Shelton and Grace published a study in JEE with Formosan termites. Transfer of fipronil from one worker to another was concentration dependent. Significant mortality occurred at >10 ppm with the most efficacious result at 100 ppm.

ENTOMOLOGIST'S RECOMMENDATIONS:

The EP/LIT labels for Termidor 80WG and Termidor SC are acceptable. BASF should submit any data remaining from the EUP trial homes tested with these products that has not been previously submitted to the EPA.

Rationale for Approval:

The product performance data and related studies submitted in support of these registration amendments showed that the EP/LIT use pattern was efficacious based on the following:

1. A low percentage of failures to the tested structures;
2. Outstanding performance in USDA-FS ground board and concrete slab testing;
3. High soil residue levels for years following application;
4. Labeling requiring (must) that an exterior perimeter treatment be made at all termite infested houses in accordance with the currently accepted label directions as described in PR Notice 96-7;
- 4a. and that a LIT be required whenever termite activity is detected inside the structure.

EPA does not believe that re-inspections should be required for the EP/LIT use pattern.

Additionally, the Agency believes that this use pattern provides additional benefits to the public health and environment because it results in the application of less fipronil. Less fipronil applied inside of residential structures reduces the potential for pesticide exposure to occupants, including children and pregnant women. Targeted applications of pesticides (as described by these labels and supported by the submitted data) are in accordance with the principles of Integrated Pest Management, an approach to pest control supported by the EPA and promoted by the Agency's Pesticide Environmental Stewardship Program (PESP).

EPA Reg. Toxicity 7969-209 + 79694210
RIN# 093405

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The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product inert impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
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