

Product Performance Study Review
by
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Insecticides Branch
August 21, 2001

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8/21/01

EPA Reg. No. 432-901

Product Name: Termidor SC

Registrant: Aventis Environmental Science

Reviewer: Ann Sibold

Product Manger: Marion Johnson, PM 10

Submission No. S601612

DP # D277044

Active Ingredients: 9.1% fipronil applied to soil at 0.06% and 0.125%

OPPTS Guideline: 810.36

Sites: Residential and commercial structures

Pests: all subterranean termite species of economic importance in the United States.

Entomologist's recommendations:

1. The submitted data meet most of the registration conditions outlined in bullets 3 & 4 of the Termidor SC registration notice for "Post-Construction Use Only" dated September 29, 1999. However, AES must add a 0.5% fipronil treatment to the CS and GB tests for Termidor SC.
2. The addition of a pre-construction use for Termidor SC is not supported by the available data and data can not be bridged from other formulations to Termidor SC for this purpose. Five years of data showing 100% control of termites at all four USDA-FS sites are required to support the registration of a pre-construction use for Termidor SC. at this time, AES has submitted only one year of test data. The second year is in progress.
3. The pre-construction language proposed in the current label amendment should be removed.

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

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4. AES must explain the lack of termite feeding pressure in untreated control plots for Termidor SC, Termidor 80WG and the 30 MEM formulation. In addition, has or will AES direct the Forest Service to establish new plots for fipronil formulations in order to determine if fipronil treatments are affecting termite populations, hence, feeding pressure at untreated controls?

5. AES must explain the lack of termite feeding pressure at the Arizona test sites for all fipronil formulations. The lack of termite feeding pressure in the controls does not refute or support the success in the treated plots. What other data are available which demonstrate control of *Heterotermes* sp. with fipronil formulations?

6. In Agency and ASPCRO discussions with AES in March 2001, AES agreed to submit or cite soil data for Termidor formulations/ fipronil. These data were to include soil residue data, soil binding data, adsorption characteristics etc. as they related to product performance. When will these data be submitted.?

7. ASPCRO should be included with all future submissions requesting a change to or addition of a soil termiticide use pattern.

8. AES should provide the Agency answers to the questions raised in this review.

Review:

Aventis Environmental Science (AES) submitted a label amendment to add pre-construction use to the Termidor SC label. AES included a justification in which they compared toxicity categories, physical/chemical properties, storage stability at one week, and efficacy data for Termidor SC to other fipronil based termiticides (registered and experimental). AES requested post-construction and pre-construction use of Termidor SC when it was first registered. Registration was allowed for the post-construction use only based on the comments below from my efficacy review dated September 28, 1999.

"...The registrant, Rhone-Poulenc requested permission to bridge the results of the 30 MEM formulation to the untested Termidor SC formulation. The 30 MEM formulation is an emulsifiable concentrate sold in France as a termiticide product. On the other hand, Termidor SC is a water soluble formulation that is to be sold in the U.S.A.. Rhone-Poulenc has concluded (or claimed) that based on the fact that results between Termidor 80 WG and 30 MEM were identical, it is the active ingredient, fipronil, which is responsible for termiticidal activity alone [therefore, the inert components act merely as a vehicle for delivery of the active ingredient to the soil].

Based on review of the Confidential Statements of Formula, (and) RD policy regarding bridging of termiticide data, I believe the efficacy data for the 30 MEM formulation can be bridged to the Termidor SC formulation. **On September 24, 1999 the Association of State Pest Control**

Regulatory Officials (ASPCRO) concurred with this recommendation by memorandum. ASPCRO and EPA recommended conditions (in bolded type) regarding product performance and labeling for registration of these products are listed below.

1. **The registrant complete a fifth year of concrete slab and ground board testing for the 30 MEM formulation at the four USDA-FS field sites and submit those data to the EPA as soon as they become available.**

2. **In addition to the USDA-FS field plots already in place for Termidor SC in Mississippi, Florida, and Arizona since February 1999; the registrant add a fourth field plot to test the Termidor SC formulation at the South Carolina USDA-FS field site by November 1999. Termidor SC plots have already been established at application concentrations of 0.03, 0.06, 0.125, and 0.25%. In addition, I request the 0.5% concentration be added to the test plots. These concentrations should be tested for five years or until the product fails. Failure in the concrete slab test at label concentrations at any USDA-FS field station will require changes to the labeled application rate and/or the product formulation. Failure in the ground board test at labeled concentrations will be reviewed on a case by case basis for its significance. The USDA-FS data on Termidor SC are to be submitted to the EPA and ASPCRO as they become available each year.**

3. **Termidor SC be registered for post-construction use only until the conditions outlined in items 1 & 2 are satisfied. Delete the pre-construction uses from the Termidor SC label. Termidor WG can be registered for pre-construction and post-construction uses...."**

It should be noted that items 1 & 2 above are the same as bullets 3 & 4 in the conditional registration notice for the subject product dated September 29, 1999 for post-construction treatment use only. **THESE CONDITIONS WERE OUTLINED FOR REGISTRATION OF THE POST-CONSTRUCTION USE ONLY. PRE-CONSTRUCTION USE APPROVAL REQUIRES FIVE YEARS OF SUCCESSFUL EFFICACY TESTING AT THE LABEL RATE AND COMMENTS AND RECOMMENDATIONS FROM ASPCRO AS OUTLINED IN PR Notice 96-7.**

In reply to my review and the conditions of registration, AES

1. submitted the fifth year report from the USDA-FS for the 30-MEM formulation;
2. established a fourth field site in South Carolina in 1999 for Termidor SC; and
3. submitted the first year progress report from the USDA-FS for Termidor SC.

However, the data submitted for Termidor SC do not include results or an indication that a 0.5% concentration has been added to the existing concrete slab (CS) and ground board (GB) test plots.

This was requested in my review and as a condition of registration and is needed since there has already been one failure in the GB test plots at the 0.25% concentration.

MRID 45452802 First Year Progress Report - Termidor SC (applied) to Soil for Control of Subterranean Termites by USDA/FS Southern Research Station, Wood Products Research, Starkville, MS

This report outlines USDA-FS testing results for Termidor SC against subterranean termites in the United States. Termidor SC achieved 100% control of termites at fipronil concentrations of 0.03%, 0.06%, 0.125%, and 0.25% in the concrete slab test at all four USDA test sites. In the ground board test, Termidor SC achieved 100% control at all four USDA sites at the same fipronil concentrations tested in the concrete slab test, - except - that one replicate was penetrated by foraging termites at 0.25% fipronil, the highest concentration tested in Arizona. The reason for the penetration does not appear to be the fault of the experimental design but rather the ability of termites to penetrate the established termiticide barrier. No other explanations were provided.

Termite feeding pressure was practically non-existent in Arizona where 100% of the untreated control plots were not attacked. Only 10% of the Mississippi control plots were attacked while termite feeding pressure was high in South Carolina and Florida.

AES should answer the following questions.

1. Is each concentration of Termidor SC established in a separate plot with an equal number of untreated controls? If not, then separate plots must be established since the possibility of a secondary kill effect due to transfer of fipronil (if this can be shown to be true - to date it has not been shown to be true) from one termite another may cause termite population suppression in the entire treatment area resulting in false negative results for the test concentrations.
2. More work needs to be done in Arizona with this formulation to insure that alkaline soils are not reducing the longevity and effectiveness of this formulation. And to insure its effectiveness against *Heterotermes* sp..

MRID 45452803 Fifth Progress Report Fipronil MEM Treatments to Soil for Control of Subterranean Termites by USDA/FS Southern Research Station, Wood Products Insect Research, Starkville, MS

Fipronil MEM is an emulsifiable concentrate formulation for termite control. The results of the fifth year progress report indicate that applications of Fipronil MEM to soil in the concrete slab test were successful for five years at all four USDA-FS field test sites at fipronil concentrations of 0.0625%, 0.125%, 0.25%, 0.50%, and 1.0%. In the ground board test, 100% control was achieved for five years at all four USDA-FS field sites at fipronil concentrations of 0.125%, 0.25%, 0.50%, and 1.0%. Two additional plots of this formulation, a CS test at

0.3125% fipronil and a GB test at 0.0625% were established in 1996 at all four test sites. The data collected through four years shows 100% termite control at each of these test concentrations.

Again, the untreated control data indicated relatively low termite feeding pressure.

MRID 45452805 Sixth Progress Report Fipronil (12VP) 80WG Treatments to Soil for Control of Subterranean Termites by Ted Roland, USDA/FS Southern Research Station, Wood Products Insect Research, Starkville, MS

The sixth progress report presents the results for Termidor 80WG for the year 2000 only. The report indicates that this formulation has provided 100% control of termites and protection of wood in treated plots for six years. In the CS test, test concentrations of Termidor 80WG were 0.0625%, 0.125%, 0.25%, 0.5% and 1.0% fipronil. In the GB test, test concentrations of Termidor 80WG were 0.25%, 0.5%, and 1.0% fipronil. In addition, four year results were reported for the concrete slab at 0.031% and for the ground board test at 0.625% and 0.125%. In both the CS and GB, the tested concentrations provided 100% control.

The untreated control replicates continue to show a low degree of termite feeding pressure. There is no explanation in the report to account for the lack of termite activity.

MRID 45452804 Second Progress Report - Evaluation of Fipronil 5 MEC Treatments to Soil for Control of Subterranean Termites in the United States by Ted Roland, USDA/FS Southern Research Station, Wood Products Insect Research, Starkville, MS

The report includes the 1999 and 2000 data for a microencapsulated fipronil formulation applied to soil in the concrete slab and ground board tests. 100% has been achieved for two years at 0.005%, 0.03%, 0.06%, 0.125%, and 0.25% fipronil in the concrete slab test at all four USDA-FS field sites. The 0.01% concentration was successful after one year of testing at all four USDA-FS sites. In the second year of testing, one replicate in Mississippi was penetrated by termites while all replicates at the other three USDA-FS sites maintained 100% control.

Unlike the plots for other fipronil formulations discussed above, the untreated controls were heavily attacked in Florida, South Carolina and Mississippi. However, the Arizona plots had no termite feeding pressure at all in the control plots.