

US EPA ARCHIVE DOCUMENT

PRODUCT PERFORMANCE DATA EVALUATION REVIEW

**Kevin J. Sweeney, Entomologist
Insecticide Branch
December 17, 2001**

Kevin J. Sweeney
12/17/01

EUP: 241-EUP-141

Section 3: 241-GOE

The results were presented in support of the Section 3 application for 241-GOE.

Product Name: PHANTOM Termiticide-Insecticide

Registrant: BASF Corporation

Reviewer: Ann Sibold

Product Manager: Marion Johnson, PM 10

Submissions: S601920 & S605807

DP: D277099 & D278957

Active Ingredient: Chlorfenapyr 21.44%.

Application Type: Liquid soil applied termiticide for post-construction use only and indoor non-food applications for cockroaches and ants. This includes residential indoor and outdoor use. Registrant claims that chlorfenapyr is not repellent to termites at label rates.

Section 3 Label application rates: 0.063%, 0.125% and 0.25%

Note: The proposed label rate of 0.063% was not tested in the USDA-FS field trials. Test plots have not been established to date.

Recommendations for Conditions of Registration:

1. Phantom termiticide may be labeled at application rates of 0.125% or higher for post-construction treatment of termite-infested structures only. Pre-construction treatments are forbidden unless data are submitted to support this treatment type based on OPPTS 810.36 guideline testing.
2. The EUP should be extended to five years for all homes in the program because of the USDA-FS trial failures. Submit the data for all EUP homes by October 31, 2004.
3. Soil residue analysis shall be continued at EUP sites and at USDA-FS sites to show that adequate chlorfenapyr is present in the soil to kill termites. Submit these data for review by October 31, 2004.
4. Soil treated at least 5 years ago with chlorfenapyr at all treatment rates (including label rates) shall be collected from USDA-FS field plots. The following termite species (members from each of three recently field collected colonies) shall be tested against the treated soil: *Reticulitermes hesperus*, *R. flavipes*, *R. virginicus*, *R. tibialis*, *Heterotermes aureus*, and *Coptotermes formosanus*. These assays shall determine the LC_{90} , LC_{95} , LC_{100} and the LT_{90} , LT_{95} , and LT_{100} for each species tested. This testing will be done according to GLP as outlined in 40CFR Part 160. Note: previously submitted data indicate an LC_{100} in the range of 25 ppm or more, not the LC_{90} of 10 ppm indicated in the final report
5. Treatment for protection of wood in direct contact with soil shall not be made.
6. Remove the 0.063% application rate from the label. It is not acceptable based on the EUP data only. The EUP data are supplemental, adding only to the confidence we have in approving the 0.125% application rate.
7. Lower label rates can only be considered after successful testing under standardized conditions as outlined in OPPTS guideline 810.36.
8. Unless data are submitted to prove the claim, the label shall not make any claims to provide area-wide control of termite populations and/or transfer of chlorfenapyr from one termite to another. As of the date of this review, these data HAVE NOT been submitted.
9. Remove the wood infesting insect section from the label. Move carpenter ants to the indoor pest control section.
10. Remove the names of the drywood and powderpost termites from the label. This includes all references to *Cryptotermes* and *Incisitermes* species. Remove all references to drywood termites and any inference or language suggesting the Phantom can be used as a preventive treatment to wood.

11. State a 4 week retreatment interval for general indoor pest control and treatment of wood infesting insects of four weeks as "Reapply if needed every 4 weeks or more."
12. For indoor pest control use, retain the 0.5% application rate. Remove the 0.25% and 0.10% application rates.
13. Remove label language pertaining to resistance management.
14. Since the general pest control use is for indoor use only, remove the term "around " from the directives for homes since "Use in and around homes" implies an allowance for outdoor pest control applications.

PRODUCT LABEL REVIEW:

The following label changes are required:

Page ONE

Page TWO

Storage and Disposal statements can be moved here to precede the "Directions for Use".

Revise First Aid Statements: Revise in accordance with PR Notice 2001-1.

Page THREE

Personal Protective Equipment

a. Non-ventilated space has not been defined. After the phrase, "non-ventilated space", insert: ", including but not limited to crawl-spaces and basements."

Pages FOUR & FIVE

Include a statement in bold typeface that states: **This product shall be used as a post-construction treatment only. Application as a pre-construction treatment is not permitted.**

Under **General Directions for Subterranean Termite Control**; second sentence, change "Theuse" to "The use".

PAGE SIX

First paragraph; delete: "Not all of the treatment directions contained in this label will be necessary to provide adequate protection against termites in every situation."

Mixing Directions:

Remove the directions for 0.063% from the entire label.

FIRST PARAGRAPH: Precede first paragraph with the heading "For mixing large volumes of finished solution":

Add a space between the words "volumes" and "prepare".

Bullet 1: add: "Filling hose must be equipped with an anti-backflow device."

SECOND PARAGRAPH: Precede the second paragraph with the heading: "For mixing small volumes of finished solution:"

Bullet 1: add "Filling hose must be equipped with an anti-backflow device."

Bullet 2: If you use the term "calibrated device"- include examples of such devices, otherwise, delete the term.

Rearrange the paragraph order as follows: Paragraph 2 should be first followed by a second paragraph that combines the content of paragraphs 1 and 3.

PAGE SEVEN:

Application Volume:

Change the sentence beginning with "Variance is ..." to read; "Variance is allowed when volume and concentration are consistent with label directed rates and a continuous barrier can still be achieved."

Add the following sentence before the sentence: "Do not treat soil...", "At reduced application volume; it may be necessary for the applicator to drill holes closer than 12 inches apart to create a continuous barrier."

Revise the next to last sentence in paragraph one to read:

Do not treat soil that is water saturated or frozen or in any conditions where run-off or movement from the treatment area (site) is likely to occur." Please refer to Jim Jones' letter dated October 9, 1997.

Explain why a table describing in-line injection is needed or remove it from the label.

General Directions for Soil Treatments:

Add: "Do not make treatments beneath slabs or similar floorings until the locations of heat or air conditioning vents, water and sewer lines, and electrical lines/conduits are known and identified. Use extreme caution to avoid puncturing and contaminating these utilities."

Accessible Crawl Spaces:

Add: "BEFORE TREATMENT: Turn off the air circulation system of the structure until application has been completed and all PHANTOM termiticide-insecticide has been absorbed by the soil."

PR Notice 96-7 contains exact standardized wording for applications to an accessible crawl space. Please replace this section with the following:

"For crawl spaces, apply vertical termiticide barriers at the rate of 4 gallons of Phantom termiticide-insecticide per 10 linear feet per foot of depth from grade to the top of the footing, or if the footing is more than 4 feet below grade, to a minimum depth of 4 feet. Apply by trenching and rodding into the trench, or trenching. Treat both sides of the foundation and around all piers and pipes. Where physical obstructions, such as concrete walkways adjacent to foundation elements, prevent trenching, treatment may be made by rodding alone. When soil type and/or conditions make trenching prohibitive, rodding may be used. When the top of the footing is exposed, the applicator must treat the soil adjacent to the footing to a depth not to exceed the bottom of the footing. Read and follow mixing and use directions on this label if situations are encountered where the soil will not accept the full application volume.

1. Rod holes and trenches must not extend below the bottom of the footing.
2. Rod holes must be spaced so as to achieve a continuous chemical barrier but in no case more than 12 inches apart.
3. Trenches must a minimum of 6 inches deep or to the bottom of the footing, whichever is less, and need not be wider than 6 inches. When trenching in sloping (tiered) soil, the trench must be stepped to ensure adequate distribution and to prevent termiticide from running off. The Phantom termiticide-insecticide solution must be mixed with the soil as it is replaced in the trench."

The language describing work to be done with mud tubes should not be a bullet to accompany the directives for what to do if the soil will not accept a full application volume.

PAGE EIGHT

Add to the end of the first paragraph:

“Read and follow mixing and directions on this label if situations are encountered where the soil will not accept the full application volume.”

Bullet 2: change “cases” to read as “case”.

Bullet 4: Add the phrase “make a horizontal treatment by applying” before the word “approximately”. Remove the word ‘apply’.

Inaccessible Crawl Spaces:

Add: “BEFORE TREATMENT: Turn off the air circulation system of the structure until application has been completed and all PHANTOM termiticide-insecticide has been absorbed by the soil.”

Slab-on-Ground: add: (including monolithic, floating and supported concrete slabs)

Divide the directions for this section based on the respective treatments: exterior (or outside) perimeter, and sub-slab injection - consisting of: vertical drilling/injection and horizontal drilling/rodding/sub-slab injection from the exterior of the foundation.

Exterior Perimeter section: Revise this section to read: “Apply by trenching and rodding into the trench or trenching around the foundation at the rate of 4 gallons finished solution (or dilution) per 10 linear feet per foot of depth, or if the footing is more than 4 feet below grade, to a depth of 4 feet. Trenches must be a minimum of 6 inches deep or to the bottom of the footing and need not be wider than 6 inches. The finished solution (or dilution) should be mixed with the soil as it is replaced in the trench. Rod holes must be spaced so as to achieve a continuous chemical barrier but in no case more than 12 inches. However, in no case should the structure be treated below the footing.”

Begin a second paragraph and insert the heading “**SUB-SLAB INJECTION**” followed by the language “Sub-slab injection treatments can be made from inside the structure or in cases where by drilling through the foundation from the outside as directed below. Prior to making any treatments, locate all heating/air conditioning ducts, vents, water/sewer lines, and electrical lines/conduits.

Insert the first sub-heading “**Vertical Drilling/Injection**” followed by the following language: To treat under the slab drill vertically through the slab along the interior perimeter of the foundation including the garage. Drill holes along all concrete expansion joints, cracks, plumbing, and utility services penetrating the slab. It may be necessary to drill holes along one side of the slab adjacent to an interior partition wall if there is clear evidence of termite activity or damage in the wall. All drill holes through the slab should be spaced so as to achieve a continuous chemical barrier but in no case be more than 12 inches apart. Inject Phantom finished solution (or dilution) into the drilled holes at the rate of 4 gallons per 10 linear feet per foot of depth. For best results, application should be made with a lateral dispersal nozzle. All holes in

commonly occupied areas into which material has been applied must be plugged. Plugs must be of a non-cellulose material or covered by an impervious, non-cellulose material.

A horizontal treated barrier can also be established beneath the slab using the above technique as a grid pattern injection. Otherwise, use the methods described below.

Insert the second sub-heading: **“Horizontal Drilling/ Rodding/sub-slab injection from the Exterior of the Foundation”** This technique should be used to treat underneath the slab only when floors or interior design do not allow for vertical drilling. Care must be exercised not to rod into heating ducts, water/sewer lines, and electrical lines/conduits. Horizontal short-rodding practices can be used to establish a continuous chemical barrier along the inside perimeter of the foundation. Holes should be drilled from outside the foundation at an angle which allows a finished solution (or dilution) of Phantom to be deposited below heating ducts, water/sewer lines, and electrical conduits if present. Horizontal long rodding practices may only be employed to treat areas underneath the slab that are not accessible by vertical rodding or horizontal short rodding. Long rods exceeding 20 feet should not be used. For all horizontal rodding applications all drill holes through the foundation should be spaced so as to achieve a continuous chemical barrier but in no case be more than 12 inches apart. Inject Phantom finished solution (or dilution) into the drilled holes at the rate of 4 gallons per 10 linear feet per foot of depth. For best results, make applications with a lateral dispersal nozzle. All holes must be plugged. Plugs must be of a non-cellulose material or covered by an impervious, non-cellulose material.

PAGE 9

Bath Traps: Why 3 gallons of Phantom dilution? What dilution(s) should be applied?

Buildings on Soil:

Change the first sentence to read: “in treating areas under wooden floors or other materials, with the exception of concrete or masonry, laying directly on or in close proximity to the soil (such as gymnasium floors, finished family rooms or similar areas converted to living areas where joists are placed on the ground and flooring placed on top), the floor should be drilled on a squared-grid pattern, 12-18 inches on center, and the Phantom dilution injected 4 to 6 inches beneath the soil surface.

Basements-outside perimeter

Add: “When trenching in sloping (tiered) soil, the trench must be stepped to ensure adequate distribution and to prevent Phantom insecticide from running out of the trench.”

Basements - inside perimeter

Add: “If a well or cistern is present, refer to wells/cisterns section of this label.”

Revise the section as follows:

“To treat under the basement floor slab, drill vertically through the slab along the interior perimeter of the foundation. Drill holes along all concrete expansion joints, cracks, plumbing, and utility services penetrating the slab. Drill holes along both sides of partition foundation walls, and around piers. It may be necessary to drill holes along one side of the slab adjacent to a non-foundation interior partition wall if there is clear evidence of termite activity in the wall. All drill holes through the slab should be spaced so as to achieve a continuous chemical barrier but in no case be more than 12 inches apart. Inject Phantom termiticide-insecticide finished solution (or dilution) into the drilled holes at the rate of 4 gallons per 10 linear feet per foot of depth. For best results, application should be made with a lateral dispersal nozzle. All holes in commonly occupied areas into which material has been applied must be plugged. Plugs must be of a non-cellulose material or covered by an impervious, non-cellulose material.”

Hollow Block Foundation or Voids:

Revise per PR Notice 96-7 as follows:

“Drill and treat voids in multiple masonry elements of the structure extending from the structure to the soil in order to create a continuous treatment barrier in the area to be treated. Apply at the rate of 2 gallons of finished solution per 10 linear feet of footing using a nozzle pressure of 25psi or less. When using this treatment, access holes must be drilled below the sill plate and should be as close as possible to the footing as practical. Treatment of voids or block or rubble foundation walls must be closely examined. Applicators must inspect areas of possible runoff as a precaution against application leakage in the treated areas. Some areas may not be treatable or may require mechanical alteration prior to treatment.

All leaks resulting in the deposition of Phantom termiticide-insecticide in locations other than those prescribed on this label must be cleaned up prior to leaving the application site. Do not allow people or pets to contact contaminated areas or to reoccupy the contaminated areas of the structure until the clean up is completed.

Not for use in voids insulated with rigid foam.”

Page 10

FOAM APPLICATIONS:

Under the heading “Foam Applications” add in bold typeface: “At least 75% of the gallons of the Phantom finished solution must be applied as a typical liquid treatment. The remaining 25% or less gallons is delivered to appropriate locations using a foam application. The total amount of product applied with the combination of foam and liquid finished solution should be equivalent to that of the application of liquid finished solution only”.

Add: "Foam applications are generally a good supplement to liquid treatments in difficult areas, but may be used in difficult to access spot treatments."

Add: "Foam applications to wall voids and stud walls must utilize dry foam only (20:1 expansion ratio)."

Add: "Foam applications to soil such as treatment of filled porches or stoops, must be done with a wet foam only (5:1 expansion ratio or less)."

Pages 11

FOAM APPLICATION USE DIRECTIONS:

Add a foam expansion ratio of 5:1 to the foam mixing table to account for any foam treatments made to soil.

PLENUMS:

Add: "BEFORE TREATMENT: Turn off the air circulation system of the structure until application has been completed and all PHANTOM termiticide-insecticide has been absorbed by the soil."

Add: "Follow the instructions below for interior treatment of plenum structures that used a sealed under-floor space to circulate heat and/or cooled air throughout the structure.

(1). Remove the sealing fabric and anything on the sealing fabric to expose no more than 18 inches adjacent to all foundation structures, including foundation walls, interior piers, pipes, and any other structures with soil contact. Follow the instructions listed above for exterior and interior treatment of "Accessible Crawl Space Construction"

(2). After the finished solution of Phantom termiticide-insecticide has been absorbed by the soil, replace the sealing fabric and anything to be placed on the sealing fabric to its original, pre-treatment position."

Page 11

Structures with Wells/Cisterns Inside Foundations:

Revise as follows based on PR Notice 96-7 and the recommendations of the U.S. EPA Environmental Fate and Effects Division.

Add the heading "**TREATMENT OF WELLS or CISTERNS**
Do not contaminate wells or cisterns."

Structures with Wells/Cisterns Inside the Foundation

a. Delete the statement: "Treat an infested and/or damaged wood in place using the injection techniques described in the Wood-infesting Insects section elsewhere in this label." Instead, suggest that wood of this nature be replaced or repaired.

b. Delete or revise "Do not treat soil while it is beneath or within the foundation or along the exterior perimeter of a structure that contains a well or cistern."

c. Revise the section to read as follows:

"Do not apply Phantom termiticide-insecticide within 5 feet of any well or cistern by rodding and/or trenching or by the backfill method. Treat soil within 5 to 10 feet of the well or cistern by the backfill method only. Treatment of soil adjacent to water pipes within 3 feet of grade should only be done by the backfill method only."

Treated Backfill Method:

Insert the language listed on Phantom insecticide-termiticide label.

Structures with Adjacent Wells/Cisterns and/or Other Water Bodies:

Add to bullet 1: "Treatment of soil adjacent to the water pipe(s) should be done according to the backfill method."

PAGE 12:

Retreatment:

Revise the last sentence to read as stated in PR Notice 96-7.

"Annual retreatment of the structure is prohibited unless there is clear evidence that reinfestation or barrier disruption has occurred."

Wood-Infesting Insects: remove this section from the label. No data were submitted to support these uses. Move carpenter ants to the indoor use section of the label.

Remove any reference whatsoever to drywood termites or non-subterranean termites..

Eliminate any inference that this product can be used in a preventive or prophylactic manner to protect wood against termites.

Pages 13 - 15

Remove all food/feed use area application directions. Chlorfenapyr does not have a tolerance for food/feed in food handling establishments.

Not for use in USDA-inspected facilities or language to that effect needs to be added.

Page 14

Remove tank mixing directions. The label states that tank mixing with pyrethroids is recommended. No data were submitted on compatibility of Phantom with any other insecticide formulation. In addition, chlorfenapyr does not have food use area approval and food/feed tolerances have not been established.

Aircraft cabin prohibition needs to be added.

Page 15

State a retreatment interval of 4 weeks based on the data submitted to support indoor cockroach and carpenter ant use. Remove the statement (listed twice) on page 15 "Repeat treatment as necessary to maintain adequate control.

Remove the 0.1 and 0.25% application rates from the indoor pest control section of the label.

Review of data submitted to support the termiticide use pattern:

MRID 454745-01 EUP Field Trials were conducted from 1998 to 1999.

Phantom was applied at concentrations of 0.063%, 0.125%, and 0.25% chlorfenapyr by PCOs to the soil at the label rate of 4 gallons of dilution per 10 linear feet per foot of depth. The treated area was approximately six inches in width. Results are presented for 1998 and 1999. These data were reviewed along with the 2000 and 2001 EUP data in the discussion for MRID 455285-01.

**MRID 454745-02 entitled: "AC 303630 Treatments to Soil for Control of Subterranean Termites: USDA Forest Service Trials" by T.A. Roland, C.D. Klein, and D.J. O'Byrne
June 4, 2001**

This submission included the Forest Service Field Trial for five years (1997 to 2001). The 2001 data for Mississippi and South Carolina were not included since these sites have not been evaluated to date. BASF explained the results for these trials, emphasizing termiticide failures where they occurred. A discussion contrasting application rates for pre- versus post-construction treatments. 1 gal dilution per 10 square feet equivalent to 0.8 pints/square foot – a pre-construction application rate versus the rate for the pending post-construction use of 4 gallons dilution per 10 linear feet per foot of depth applied to a six-inch wide area. BASF claims that the USDA-FS test simulates a pre-construction treatment and as a result, the amount of chlorfenapyr applied to equal volumes of soil is lower for a pre-construction treatment versus the proposed labeling for post-construction only.

A complete review of the USDA and EUP data is summarized below.

MRID 455285-01 Phantom termiticide-insecticide Registration Application for Non-food Use, EPA File Symbol 241-GOE dated October 25, 2001.

This volume summarized EUP and USDA-FS product performance trials and is divided into 18 exhibits. Data are reported for 1998, 1999, and 2000 sites through 2001. The results from 501 homes are presented.

Exhibit 17 Fifth Progress Report: AC 303,630 (chlorfenapyr) Treatments to Soil for Control of Subterranean Termites (in cooperation with BASF Corporation)

As discussed in previous reviews on chlorfenapyr product performance data, the results of the U.S. Forest Service fields trials are variable and do not appear to be dose dependent or site specific. Termite foraging activity - as indicated by the untreated control results - was high and sustained during most of these field tests. The exception was in Arizona where termite foraging

activity was low in both the ground board and concrete slab tests from 1997 to 1999. However, termite activity increased dramatically in 2000 and 2001 at the Arizona site.

The Forest Service uses its own rating system to assess and characterize damage to wood at penetrated replicates. According to BASF, a FS rating of 2 is equivalent to an ASTM rating of 9; a damage rating of 3 is equivalent to an ASTM rating of 7. Damaged boards are replaced each year (The possible impact of this action on the experimental results of from these tests requires closer scrutiny).

A "failure" as defined below means that termites survived exposure to the termiticide treatment and were able to feed on the wood in the treated plots. This is in keeping with OPPTS 810.36 series guidelines for a soil-applied termiticide.

USDA-FS Concrete Slab Tests

Soil below the concrete slab is treated and wood bait blocks are placed on a circular area of treated soil in the center of the slab.

Arizona: no failures for five years.

South Carolina: no failures for five years.

Failures were as follows (Note: none of the treated replicates suffered repeat attacks):

Florida:

0.75% - Termites penetrated two of 10 replicates in the 0.75% chlorfenapyr treatment (3x the label rate) in 1998. Termite damage to the wood boards was characterized as "light" the by Forest Service.

0.125% - Failures were observed in 0.125% chlorfenapyr treatments (label rate) in 1 of 10 replicates in 1998 and 1 of 10 replicates in 2000. Wood damage was characterized as "heavy" in 1998 and "moderate" in 2000. All penetrations by termites were made at different replicates.

Mississippi:

0.125% - 3 of 10 replicates in 1998 and 1 replicate of 10 in 1999 were attacked at the 0.125% rate.

0.25% - termites attacked 1 of 10 replicates in the 0.25% chlorfenapyr treatment in 1999 and in 1 of 10 replicates in 2001.

0.5% - In 2001, 1 of 10 replicates was attacked at 0.5% chlorfenapyr treatment.

2.0% - Termites attacked 1 of 10 replicates in the 2.0% chlorfenapyr treatment and 3 of 10 at the 0.125% rate in 1998. Only one of the attacked treatments in MS exhibited moderate damage. The other damaged MS replicates suffered surface etching only.

BASF believes that the reasons termites survived long enough to attack wood in the USDA-FS plots while exposed to the label rate concentrations proposed for termite control applications was because chlorfenapyr, as an uncoupler of oxidative phosphorylation and a non-repellent, kills termites slowly. Of the 13 replicates attacked across all concentrations of chlorfenapyr over the 5-year testing period, 3 (approx 25%) had active termites at the time of inspection. Based on the control data below, the expected % was 63% or 8 replicates. Active termites were found in both Florida and Mississippi. Termite activity did not occur at the same penetrated replicate more than once.

Of the 105 penetrated control replicates, 67 (63%) had active termites present at the time of inspection. Termites reoccurred at many of the untreated replicates even though wood blocks were replaced each year.

We do not know if the 40% difference between the treated and untreated replicates is statistically significant. I am uncertain if the 3 observed vs. 8 expected replicates is attributable to the action of chlorfenapyr or simply an experimental design effect.

USDA-FS Ground Board Tests

The 0.25% label rate was tested along with 0.5%, 0.75%, 1.0%, and 2.0% chlorfenapyr concentrations at all four USDA-FS field sites.

Test failures (Note: none of the treated replicates suffered repeat attack)

0.25% - Termites penetrated the 0.25% chlorfenapyr rate in 2 of 10 replicates in Florida in 1997 and in 1 of 10 replicates in 1999 in Mississippi. Termite damage was light to moderate in the attacked replicates.

0.5% - In Florida, termite penetrations also occurred at the 0.5% rate in 1 of 10 replicates in 1998 and at the 0.75% rate in 1 of 10 replicates in 2001. Termite damage was light to moderate in the attacked replicates.

Termite activity at the time of inspection: Of the penetrated plots in the GB tests, 2 out of the 5 (40%) replicates had active termites at the time of inspection. On the other hand, 114 of 150 (76%) untreated control replicates had termite activity at the time of inspection. We do not know if the difference in % activity between treated and untreated replicates is significant or in any way related to the chlorfenapyr treatments. It does appear to agree with the difference found in the CS tests.

Conclusion:

1. The data show that chlorfenapyr termiticide treatments **DO NOT** affect termite populations over a large area. Otherwise, the untreated control replicates within the test plots would decline over time. This did not occur. No evidence was presented to show that chlorfenapyr is transferred from one termite to another.
2. The results with the concrete slab and ground board tests test show mixed successes at the concentrations tested. Failures occurred throughout the range of concentrations tested – from highest to lowest – unlike most termiticides where treatment success appears to depend upon dose and can be related to toxicological principles such as a dose-response relationship.

EXHIBIT 18 - Soil Residue Analysis from USDA-FS test plots and EUP sites.

In addition to the test plots for termiticide evaluations, plots are established in the USDA-FS trials to determine the residual life of chlorfenapyr in treated soil over time. Chlorfenapyr residues were measured for all concentrations tested in the CS and GB tests each year for five years. Untreated control replicates were also evaluated for comparative purpose. Only chemical assays for residue were performed. Bioassays against termite populations in the laboratory were not done with the field treated soil but probably should be to show that the treated soil can still kill termites after five years. Instead, BASF has compared the collected residue data to a series of laboratory bioassays with chlorfenapyr treated soil stored in lab over a two-year period.

Residue data are presented in tables and graphs. The tables include the mean, standard deviation for each mean, and the low and high levels in the respective field trials. The graphs were plotted using the mean values as data points without presenting the confidence intervals. These plots depict trends and differences but since the confidence intervals are not shown on the graph, we cannot determine if the plotted lines are significantly different from one another. A statistical analysis was not presented to show whether or not the lines differed from one another. In addition, the scales of each plot are not the same, making direct visual comparison of the plotted data more difficult. None of residue data show a consistent rate of decay or a definitive half-life. Contrary to popular belief, chlorfenapyr does not appear to be longer-lived than many other termiticides currently registered – at least based on the results of these submitted studies.

The plotted data show that chlorfenapyr is residual and that nearly all replicates retained enough chlorfenapyr over the course of the study (five years) to kill termites based on an LC90 value of 10ppm in soil. However, USDA-FS lab studies showed that 100% of the termites were killed when challenged with aged soil at chlorfenapyr concentrations of 25ppm or more. The residue data from field trials indicates that 25ppm chlorfenapyr - on average - is present in the soil at the end of five years in most USDA-FS sites with higher concentrations detected at EUP sites. How much of the residue is available as a toxicant to termites? We really don't know since chlorfenapyr binds tightly to soil.

EXHIBITS 2 to 16 list EUP Results 1998-2001 at approximate 500 treated homes in the United States.

The EUP provided the registrant, PCOs, and regulatory community with an opportunity to witness the effectiveness of these applications under actual use conditions. Phantom termiticide was applied to approximately 500 EUP homes throughout the United States. Most of the homes were located in the Southeastern U.S. The chlorfenapyr concentrations tested were 0.0625%, 0.125% and 0.25%. Of these, the 0.0625% rate WAS NOT evaluated in the USDA-FS field trials. In the majority of the treated homes, termites infesting these structures have been killed and a retreatment has not been necessary. The EUP results to date are encouraging and indicate that chlorfenapyr has a strong potential as a soil applied termiticide.

However, these data are considered SUPPLEMENTAL to the standardized field test results conducted by the USDA-FS because the environmental conditions existing at homes are highly variable. In order to evaluate these data using the scientific method, more termite population monitoring would be required, homes of identical construction selected and compared, and applications would need to be made by the same individuals using the same equipment. Support for this position comes from the EUP data set itself. Upon more careful review of these data, there appears to be some variation in the amount of Phantom end-use dilution applied to homes of similar square footage, linear feet, and construction type. For instance, Exhibit 5 lists EUP homes in Arizona. Of the homes treated at the 0.125% rate by the same applicator, Truly Nolan, 131 gallons of solution was applied to 8DAZ2 while 220 gallons was applied to 8DAZ5. Both homes were floating slab construction. 8DAZ2 was a 1400 square foot homes with 313 linear feet of possible treatment footage while 8DAZ5 was a 954 square foot home with 318 linear feet of treatment footage. Roughly calculated, 8DAZ2 was treated at the rate of 3 gallons per 10 linear feet to the depth of the footer while 8DAZ5 was treated the rate of 6.1 gallons per 10 linear feet to the depth of the footer. No explanation is provided as to why different amounts were applied or if more of one structure had to be treated than another. It is assumed that both were treated to a foot of depth due to the construction type. In this example, the same applicator, construction type, and termite species existed yet the treatment was different based on the amount of Phantom applied. The amount of chlorfenapyr applied per linear and square foot was greatly different. Other examples of the same situation exist in the data set for all rates tested. This type of situation makes a quantitative analysis almost meaningless and leaves evaluation to a less sensitive qualitative method. Standardized testing using USDA-FS, though not as realistic, provides a better opportunity to control experimental variables and conditions, have a valid negative control treatment – and – most importantly – it can be repeated with the same or very similar results by the same or different applicators, and same termite species, plot type, and environmental conditions. A direct comparison of the same application type and amount of chlorfenapyr applied to the same type of soil is possible and valid. This is not to say that the EUP are of no value but they aren't collected under a controlled experimental design like the FS data are. Therefore, I do not believe a label rate for Phantom should be approved based upon EUP data only.

Given the submitted USDA-FS data and the EUP results, I recommend that the EUP be extended to December 31, 2004 and that five years of data be collected under the EUP for all 500 homes. In addition, residue data must continue to be collected at EUP sites and at USDA-FS to insure that enough chlorfenapyr is available to kill termites and to better define the fate of chlorfenapyr as a termiticide.