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

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 26 November 2001

SUBJECT: **CHLORFENAPYR** - Review of *Phantom™ (Chlorfenapyr-CL 30630): Determination of Indoor Air Concentrations of Chlorfenapyr after Application of PHANTOM™ 2SC Termiticide-Insecticide Applied as a Termiticide Treatment to Basement and Crawl Space Construction Housing.* PC Code: 129093. DP Code: 266948. MRID: 45137301.

FROM: Mark I. Dow, Ph.D., Biologist
Registration Action Branch 1
Health Effects Division 7509C

THROUGH: G. Jeffrey Herndon, Branch Senior Scientist
Registration Action Branch 1
Health Effects Division 7509C

TO: Ann Sibold
Insecticides Branch
Registration Division 7505C

INTRODUCTION

On 31 October 2001 Versar Inc. conducted a primary review of the subject study. This memorandum constitutes the Health Effects Division's (HED) secondary evaluation and notification to the Registration Division. The American Cyanamid Company contracted the subject study to determine what, if any, airborne residues of chlorfenapyr might occur as a result of typical post-construction termiticide application. In this study four structures (occupied residences) were treated. Two had basement style construction and two had crawl space construction. In each structure, a stationary air sampling pump was set up in the basement or crawl space, in a first floor bedroom or family room and in the kitchen. Sampling took place as follows: application, during application, immediately after application, and on DAT 3, DAT 7 and DAT 30-31. Samples were not collected from the basements or crawl spaces during application. Chlorfenapyr was not detected in any of the samples from any of the four structures.

DISCUSSION

The Versar review lists a number of "concerns" relative to the study and the Guidelines. See the "attachment" for a copy of the review. A list of "concerns" and HEDs discussion of them are in the APPENDIX. HED basically agrees, in the technical sense, with the concerns noted by Versar. However, HED notes that the Guidelines are in fact "guidelines" and while the study does not strictly adhere to the Guidelines in some senses, the results are still useful.

HED notes that "No chlorfenapyr residues were found in any room in any residence during this study (LOQ <0.18 µg or <0.5 ng/L air filtered for 6 hours at 1 Lpm)." Further, a set of weathered and non-weathered field fortification samples was generated at each house to be monitored prior to the treatment date. On the day of pretreatment sampling at each house, six labeled sorbent tubes were fortified with analytical grade chlorfenapyr in solvent at 10 x LOQ (1.8 micrograms). The LOQ was 0.18 µg which provided an LOQ of 0.5 nanograms/L when filtered for a six hour collection time at a flow rate of 1 L/min.

Field fortification results ranged from 91% to 104% recovery for travel spikes and 90% to 102% recovery for the weathered field spikes.

HED agrees with Versar that it is desirable to have a documented Level of Detection. Also, while the study indicates that spikes were analyzed at the LOQ and at 10 x the LOQ, actually only the higher level was evidently analyzed.

SUMMARY

Although there are technical deviations from the Guidelines, in light of several factors such as the recovery efficiencies, the physical/chemical properties of chlorfenapyr (i.e., vapor pressure $<1.0 \times 10^{-7}$) and the pesticide delivery methods which don't produce aerosols, HED finds the study acceptable and useful in the characterization of possible airborne residues under these circumstances. Actually, the reported results coincide with HEDs theoretical assessment of inhalation exposure based on the Ideal Gas Law (see DP 277150). In that assessment, assuming atmospheric **saturation**, resulting MOEs were all > 4000 for all exposure time periods.

APPENDIX

The following discussion is taken, in part, from Versar's review "COMPLIANCE CHECKLIST" which is a discussion of the major aspects of OPPTS Series 875 Occupational and Residential Exposure Test Guidelines, specifically Series 875.2500 for inhalation exposure monitoring. Only those "criteria" which were viewed by Versar as not being met are discussed.

1) The monitoring period should be of sufficient duration to result in reasonable detectability on dosimeters. Monitoring should be conducted before residues have dissipated beyond the limit of quantification. Baseline samples should be collected before the exposure activity commences. This criterion was not met. Residues were not detectable on any of the air sampling tubes collected on any of the sampling days. This included the day of application.

HED notes from the study: "A set of weathered and non-weathered field fortification samples was generated at each house to be monitored prior to the treatment date. On the day of pretreatment sampling at each house, six labeled sorbent tubes were fortified with analytical grade chlorfenapyr in solvent at 10 x LOQ (1.8 micrograms). The LOQ was 0.19 µg which provided a LOQ of 0.5 **nanograms/L** (emphasis added), when filtered for a 6 hour collection time at a flow rate of 1 L/min." "A second labeled set of triplicate fortified samples plus control were placed on the Agrisearch Incorporated Spikemaster (calibrated air chamber drawing air through multiple air tubes at the same rate) in one of the rooms and run at 1 Lpm for 6 hours (the maximum length of sampling time for samples in this study)." HED notes further that samples were collected "pre-application, immediately after application (**0.1 DAT**) (emphasis added) and 3, 7, 30 and 31 DAT. Clearly every attempt was made to capture whatever measurable residue might exist. In light of the sensitivity of the LOQ and the timing of the initiation of sampling, measurable residues could not have dissipated. Baseline samples were collected prior to treatment. This is not of concern to HED

2) *Studies should be conducted under different geographic/climatologic sites.* This criterion was not met. All four houses were in the same geographic region (Frederick, Maryland).

HED notes that this criterion is primarily relative to agricultural situations where differences in climate and cultural practices may affect certain study results. In this situation, this is not of concern to HED.

3) *Particulate levels should be monitored along with vapor phase concentrations unless adequate justification for not doing so is provided.* This criterion was not met. A justification for not monitoring both particulate and vapor phase concentrations of chlorfenapyr was not provided in either the study protocol or the study report.

Particulates would not be expected from a liquid spray delivery system as might be expected from granulars or dusts. Further, "fines" such as aerosols are next expected by HED under these application parameters. This is not of concern to HED.

4) *Retention and breakthrough studies should be performed under conditions similar to those anticipated in the field phase of the study.* This criterion was not met. Formal retention and breakthrough studies were not performed prior to this study. The study report states that the field fortification recovery results supports that breakthrough did not occur.

This criterion is intended primarily for other types of dosimetry (i.e., patches) and is not of concern to HED in this case.

5) *Stationary samples should be collected from the center of treated fields and from at least 4 other locations, preferably at the cardinal compost points from the center location.* This criterion was not met. Only 3 indoor locations were used to collect air samples. One air monitoring pump was placed in the basement or crawl space of each house where the applications took place. Whether or not these were placed in the center of the treated area is not known.

This criterion is intended primarily for agricultural situations. This is not applicable in this study situation and is not of concern to HED.

6) *Validated analytical methods of sufficient sensitivity are needed. Information on method efficiency (residue recovery) and limit of quantification (LOQ) should be provided.* This criterion was not met. Method validation information was not provided supporting sufficient sensitivity. The linear range of the GC/NICIMS was not provided, but the LOQ was (0.18 µg).

HED agrees that it is desirable to have validated methods of LOD. However in light of the LOQ (0.18 µg), and the weathered and non-weathered spikes as discussed earlier, this not of concern in this case.

ATTACHMENT

Reviewer: Teri D. Schaeffer /Marit Espevik **Date October 31, 2001**

STUDY TYPE: Residential Post Application Indoor Air Monitoring Study

TEST MATERIAL: PHANTOM™ 2SC Termiticide-Insecticide is formulated as a 21.44% suspension concentrate of the active ingredient 4-bromo-2-(4-chlorophenyl)-1-(ethyoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile (CAS No. 122453-73-0).

SYNONYMS: The active ingredient is also known as chlorfenapyr or CL 303630.

CITATION:

Study Director:	D. Larry Merricks, PhD
Title:	*PHANTOM™ (Chlorfenapyr-CL 303630): Determination of Indoor Air Concentrations of Chlorfenapyr after Application of PHANTOM™ 2SC Termiticide-Insecticide Applied as a Termiticide Treatment to Basement an Crawl Space Construction Housing.*
Report Date:	April 21, 2000
Laboratories:	Agrisearch Incorporated 5734 Industry Lane Frederick, MD 21704-7293 American Cyanamid Company Agricultural Products Research Division P.O. Box 400 Princeton, NJ 08543-0400
Identifying Codes:	MRID 451373-01; Laboratory Project Identification Number RES 00-011; American Cyanamid Study Number EEA 98-007; Agrisearch Study Number 3803. Unpublished.

SPONSOR: American Cyanamid Company
Agricultural Products Research Division
P.O. Box 400
Princeton, NJ 08543

EXECUTIVE SUMMARY:

The purpose of this study was to determine the indoor air concentrations of chlorfenapyr in a residential room and basement crawl space air after a single termiticide treatment of PHANTOM™ 2SC Termiticide-Insecticide to basement and crawl space construction housing. Four houses (two with basements and two with crawl spaces) were treated with the test product. Each house was treated at the maximum label rate of 4.8 lbs ai/100 gallons finished spray. The spray was made up of 2.4 gallons of formulation mixed with 97.6 gallons of water. It was applied at 1 gallon of finished spray solution per 10 square feet. All treatments took place in December 1998.

Chlorfenapyr residues were not detected in any of the air monitoring samples collected at any of the four residences. The LOQ was 0.18 µg (or 0.5 ng/L air filtered for 6 hours at 1 Lpm). The quality control samples supported good field and laboratory techniques as well as stability of the active ingredient in storage for up to 328 days. However, the field fortification samples were only prepared at one fortification level (1.8 µg or 10x LOQ). Field fortification samples should also have been prepared at the LOQ to demonstrate the stability of the active ingredient at low level concentrations.

The study was reviewed using the OPPTS Guidelines Series 875, Part B: Inhalation Exposure Monitoring Guidelines 875.2500. This study met most of the Series 875.2500 Guidelines (see Appendix A). The following issues of concern are noted:

- The study did not result in any useable data from any of the four test sites. All chlorfenapyr residues found in all field samples were below the LOQ. This may indicate that sufficiently low LOQ and LOD were not achieved.
- Monitoring should have been conducted before the residues dissipated beyond the limit of quantification. Although sampling occurred during the application and immediately after the application, detectable chlorfenapyr residues were not found.
- According to the guidelines, studies should be conducted under different geographic/climatologic sites. For this study, all four houses were in the same geographic region (Frederick, Maryland).
- Inhalation monitoring techniques, in this case stationary air monitoring, should contain sufficient samples to characterize the likely range of possible exposure concentrations. Only three samples per house were collected per sampling event, but none of the three samples contained detectable concentrations of chlorfenapyr.
- Validated analytical methods of sufficient sensitivity are needed. Method validation information supporting sufficient sensitivity was not provided. The linear range of the GC/NICIMS was not provided, but the LOQ was (0.18 µg).
- Information on recovery samples must be included in the study report. A complete set of field recoveries should consist of at least one blank control sample and three or more each of a low-level and high-level fortification. These fortifications should be in the range of anticipated residue levels in the field study. For this study, field fortification recovery data were provided in the study report, with one blank control per fortification sample. However, there was only one fortification level. This fortification level was ten times the LOQ. A fortification level prepared at the LOQ should have been done as well, since there were no detectable levels of chlorfenapyr in the samples. The field fortification samples were said to support storage stability, hut there were no low level fortification samples to determine how stable low levels of chlorfenapyr were.
- Particulate levels should be monitored along with vapor phase concentrations unless adequate justification for not doing so is provided. Such a justification was not provided in either the study protocol or the study report.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study sponsor waived claims of confidentiality within the scope of FIFRA Section 10(d) (1)

(A), (B), or (C). The study sponsor and author stated that the study was conducted under EPA Good Laboratory Practice Standards (40 CFR part 160), with only one exception. The one exception was that the site histories for each test site were not GLP compliant.

CONCURRENT DISLODGEABLE RESIDUE DISSIPATION STUDY?: No

GUIDELINE OR PROTOCOL FOLLOWED:

The study followed OPPTS Series 875, Part B: Inhalation Exposure Guidelines 875.2500. The protocol number was EEA 98-007.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material:

Formulation:	PHANTOM™ 2SC Termiticide-Insecticide is formulated as a 21.44% suspension concentrate (2 lbs ai per gallon) of the active ingredient 4-bromo-2-(4-chlorophenyl)-1-(ethyoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile.
Lot/Batch # technical:	AC 9389-90
Lot/Batch # formulation:	AC 11694-4U
Purity:	Chlorfenapyr analytical standard was characterized with a purity of 99.7% (expiration data of 4/13/01).
CAS #(s):	CAS number for chlorfenapyr is 122453-73-0.
Other Relevant Information:	EPA Registration No. is not yet available. Source of the test substance was American Cyanamid Company.

2. Relevance of Test Material to Proposed Formulation(s):

The study refers to the test product as PHANTOM™ 2SC Termiticide-Insecticide. The label provided with the study is for Chlorfenapyr Termiticide-Insecticide. Both appear to refer to the same product.

B. STUDY DESIGN

There were 6 amendments to the protocol and 11 deviations from the protocol. The protocol amendments referred to laboratory and personnel changes as well as analytical time frames, tank mix analytical procedure, air tube analytical procedure, and changes to Method 2471. The deviations from the protocol included (1) placement of air samplers due to differences in floor plan; (2) height of samplers in crawl spaces due to space constraints; (3) time samples were placed in freezer not being recorded; (4) omission of fortification of a "field fortification sample"; (5) failing to mix soil after application as per protocol; (6) failing to keep equipment cleaning log ; (7) samples not analyzed in order set by protocol; (8) distances between test substance treatment sites and air samplers not being measured; (9) using a calibrated flow meter to determine amount of test substance applied; (10) collection of sample product just prior to application of the first tank at each house; and (11) not recording the air flow patterns of each house. The study author indicated that none of the amendments or deviations had an impact on the integrity of the data in this study.

1. Site Descriptions:

The study used four different residential houses located in Frederick, Maryland (Frederick County). Two houses had basements and two had crawl spaces. The ages of the houses ranged from 30 to more than 200 years. All four houses were occupied during the application and sampling events. The following is a brief description of each house, along with the square footage and volume, not including the basement or crawl space.

House 1: An unmodified split level brick home with a total area of 1,847 ft^2 and a volume of 14,475 ft^3.

House 2: A multistory brick home with several additions with a total area of 3,155 ft^2 and a volume of 26,977 ft^3.

House 3: A small home of wood siding with a total area of 790 ft^2 and volume of 5,530 ft^3.

House 4: A wooden structure with multiple additions with a total area of 1,905 ft^2 and volume 14,288 ft^3.

2. Application Rates and Regimes:

Application Rate(s): The application rate used in this study was the maximum proposed label rate of 4.8 lb ai per 100 gallons of finished spray. The spray was made up of 2.4 gallons formulation in 97.6 gallons of water (for a total of 100 gallons finished spray). One gallon of finished spray was applied per 10 square feet. Each gallon of formulation contained 2 pounds of the active ingredient chlorfenapyr, which equates to 4.8 lbs ai/1000 square feet.

Table II in the Study Report presented total chlorfenapyr (a.i.) applied to each of the four houses: House 1: 4.08 lbs, House 2: 7.92 lbs, House 3: 2.16 lbs, and House 4: 4.08 lbs.

Application Regime: The test product was applied to all four houses in December 1998. Prior to application of the test product, each crawl space house was prepared by either digging a trench 6 inches deep and 6 inches wide around the perimeter or by drilling a ½ inch hole through concrete slabs. The concrete slabs or foundation walls of the two basement houses were drilled on 12 inch centers to deliver pesticide along the outside surface of foundations. A single application was made at each location by spraying into the trench around the exterior of each house using the gun or by applying 0.4 gallons spray into each drilled hole. The application rate was monitored using a flow meter which was placed in-line before the nozzle. After the application, each hole was filled with concrete and caulk to seal the chemical below grade or to seal basement walls or slabs. All of the outside trenches were closed.

Application Equipment: The equipment used was a Hypro Corp Model D30 spray pump system incorporating recirculation to the 100 gallon tank, for solution agitation. A flow meter was placed in-line between the hose and the handgun.

Spray Volume: 1 gallon spray per 10 square feet.

Equipment Calibration Procedures: The spray gun used for broadcast application as well as the rod tip attachment used for application into holes was calibrated prior to use in the study. The equipment was operated at a pressure of 25 psi as per the study protocol. The calibration procedure involved the use of graduated cylinders and the in-line flow meter. The results of the calibration procedure were tabulated in the study report on page 14.

4. Replicates:

In each home, a stationary sampling pump was set up in the basement or crawl space, in a first floor bedroom or family room, and in the kitchen. In house 1, the air samplers were placed in the basement, kitchen and family room. In house 2, the air samplers were placed in the basement, kitchen and parlor. In house 3, the air samplers were placed in the crawl space, kitchen and bedroom. In house 4, the air samplers were placed in the crawl space, kitchen and bedroom. Floor plans of each house sampled (showing area and volume) was presented on pages 24-28 of the Study Report.

5. Sampling Schedule:

One sorbent tube sample was collected from each stationary sampling pump in each location within the house. The sampling schedule took place as follows: application, during application, immediately after application, and on DAT3, DAT7, and DAT30-31. Samples were not collected from the basements or crawl spaces during the application.

6. Air monitoring methodology:

Each sampling pump was pre-calibrated to deliver a 1.0 Lpm flow rate on each sampling day. Each pump was fitted with a fresh sorbent tube containing XAD-2 resin with the tube opening located approximately 36 inches above floor level. The pumps ran for 6 hours and were then turned off (except for the sampling event during application). The flow rates for each sampling pump was re-checked after each sampling event. Each sorbent tube sample was removed, capped at each end and placed into prelabeled Ziploc® bags and placed into a small cooler for transport to the Agrisearch facility.

Temperature and relative humidity were recorded on each sampling day. The following is a brief summary of the climatic conditions at each test location:

House 1: (basement)	The temperatures at the first floor level and the lower level during the application were 69°F and 70°F. The temperatures for both of these levels for all of the sampling days ranged from 57°F to 72°F. The relative humidity at the first floor level and the lower level during the application was 38%. The relative humidity for both levels ranged from 35% to 60%. Outside temperature and humidity were also recorded on the day of application. The outside temperature and humidity at this test site was 38°F and 38%, respectively.
House 2: (basement)	The temperatures at the first floor level and the lower level during the application were 65°F and 63°F. The temperatures for both of these levels for all of the sampling days ranged from 62°F to 68°F. The relative humidity at the first floor level and the lower level during the application was 35%. The relative humidity for both levels ranged from 31% to 49%. Outside temperature and humidity were also recorded on the day of application. The outside temperature and humidity at this test site was 36°F and 38%, respectively.
House 3: (crawlspace)	The temperatures at the first floor level and the lower level during the application were 69°F and 65°F. The temperatures for both of these levels for all of the sampling days ranged from 58°F to 74°F. The relative humidities for the first floor level and the lower level during the application were 44% and 36%. The relative humidity for both levels ranged from 31% to 70%. Outside temperature and humidity were also recorded on the day of application. The outside temperature and humidity at this test site was 55°F and 36%, respectively.
House 4: (crawlspace)	The temperatures at the first floor level and the lower level during the application were 71°F and 64°F. The temperatures for both of these levels for all of the sampling days ranged from 36°F to 82°F. The relative humidities for the first floor level and the lower level during the application were 48% and 50%. The relative humidity for both levels ranged from 24% and 62%. Outside temperature and humidity were also recorded on the day of application. The outside temperature and humidity at this test site was 50°F and 75%, respectively. A light rain occurred at this test site several hours prior to the application.

7. Sample Handling:

The samples which were collected at each house on each day were placed together in a larger Ziploc® bag and immediately put onto dry ice in the field for transport to the Agrisearch facility. At the Agrisearch facility the samples were placed in frozen storage (≤ -10°C) prior to shipment to the American Cyanamid Company. Sample shipments arrived at ACCO on January 6, 7, and 20, 1999. The samples were stored in a walk-in freezer maintained at ≤ -10°C until analysis. The samples were analyzed by ACCO laboratory personnel between October 24, 1999 and November 5, 1999.

Sample storage ranged from 288 to 328 days prior to analysis. The sample stored for 328 days was a field fortified sample. Therefore, field fortification recoveries were used to demonstrate storage stability of the active ingredient from sample collection through sample analysis.

8. Analytical Methodology:

Extraction method(s): The samples were prepared for analysis using American Cyanamid's SOP ES.R.0507. In this procedure the chlorfenapyr residues were extracted from the air sampling tubes with acetone. The acetone extract was analyzed for chlorfenapyr by gas chromatography/negative ion chemical ionization mass spectrometry (GC/NICIMS). A detailed description of the extraction procedure was not provided in the study report. Table 1 provides a summary of the analytical conditions used to measure chlorfenapyr.

Detection method(s):

Table 1. Summary of GC/NICIMS Conditions

GC Column	J & W Scientific silica capillary column DB-5MS bonded phase 5 m x 0.25 mm i.d. 0.25 µm film thickness
Temperatures	Column: 60 °C 0.0 minutes 60 °C 0.5 minutes 250 °C 13.2 minutes Injector: 270 °C
Injection Volume	1 µL
Retention Times	Chlorfenapyr at 7 minutes and 54 seconds
Linear Range	Not provided

Method validation: Air tube samples were analyzed following American Cyanamid draft method M 2471.01. The validated limit of quantification (LOQ) was 0.18 µg or 0.5 ng/L air filtered for 6 hours at 1 Lpm. A limit of detection (LOD) was not provided in the study report.

Instrument performance and calibration: Information about the calibration curve ran prior to sample analysis was not provided in the study report.

Quantification: The formulas used to calculate percent recoveries and field residues were presented on page 79 of the study report.

9. Quality Control:

Lab Recovery: As a measure of laboratory quality control, concurrent laboratory fortified samples were analyzed with the field samples. The laboratory fortified samples were fortified at 0.18 µg and 1.8 µg (0.5 ng/L and 5.0 ng/L). Laboratory fortified recoveries ranged from 92% to 106% with an overall average recovery of 98% ± 4%. The number of replicates per fortification level and the individual replicate recoveries were not provided in the study report.

Field blanks: Two control samples were prepared with the field fortification samples. One control sample was prepared with the non-weathered fortified samples and the other was prepared with the weathered fortified samples. The control samples showed no recoveries above the LOQ (0.18 µg).

Field recovery: A set of weathered and non-weathered field fortification samples was generated at each house to be monitored prior to the application date. The field fortification samples were prepared at only one fortification level. On the day before application, six labelled sorbent tubes were fortified with analytical grade chlorfenapyr in solvent at ten times the LOQ (1.8 µg or 5.0 ng/L) at each house. One control plus the triplicate sorbent tubes were collected, capped at each end, placed in Ziploc® bags and placed in frozen storage immediately after fortification. These samples represented "non-weathered" travel spikes. A second labelled set of triplicate fortified samples plus control were placed on the Agrisearch Incorporated Spikemaster (calibrated air chamber drawing air through multiple air tubes at the same rate) in one of the rooms and run at 1 Lpm for 6 hours (the maximum length of sampling time for samples in this study). After 6 hours, these samples were collected, capped at each end, placed in Ziploc® bags and placed in frozen storage as weathered field spikes. The results from the field fortification analyses showed that chlorfenapyr did not break through solvent tubes filtering at 1 Lpm for 6 hours, and that it was stable during sample collection and storage. Field fortification results ranged from 91% to 104% recovery for the non-weathered ("travel spikes") fortification samples and from 90% to 102% for the weathered field fortification samples. Table 2 shows a summary of these results.

Table 2. Field Fortification (Weathered and Non-Weathered) Recoveries

House	Chlorfenapyr Fortification Level (ng/L)[a]	Type of Fortification Sample	Recovery (%)	Overall Average Recovery (%)	Standard Deviation
1	5	Non-Weathered	103	98.3	4.2
	5	Non-Weathered	104		
	5	Non-Weathered	101		
2	5	Non-Weathered	102		
	5	Non-Weathered	100		
	5	Non-Weathered	94		
3	5	Non-Weathered	91		
	5	Non-Weathered	101		
	5	Non-Weathered	94		
4	5	Non-Weathered	97		
	5	Non-Weathered	99		
	5	Non-Weathered	94		
1	5	Weathered	96	97.1	3.9
	5	Weathered	94		
	5	Weathered	101		
2	5	Weathered	98		
	5	Weathered	0[b]		
	5	Weathered	100		
3	5	Weathered	100		
	5	Weathered	102		
	5	Weathered	99		
4	5	Weathered	90		
	5	Weathered	96		
	5	Weathered	92		

a A 1.8 µg fortification level represents 5.0 ng/L based on 360 Liters air flow. However, non-weathered samples had no air flow.
b This field fortification sample was accidentally not spiked.

Formulation: Duplicate analyses of the product sample taken at the time of the test substance application determined that the formulation contained an average of 21.40% active ingredient using Method M 2287.02.

Tank mix: Two samples of the tank mix were collected prior to application. Two additional tank mix samples were collected immediately after the completion of treatment of each house. All of the tank mix samples were placed on dry ice in the field and then transported to frozen storage. The results from the tank mix analyses showed that the finished spray solutions were mixed at the correct levels. Chlorfenapyr percent recoveries from the tank mix samples ranged from 84.3% to 104.2%. The overall average percent recovery was 97.9% $\pm$ 7%.

Storage Stability: A separate storage stability study was not performed for this study. However, the field fortification recoveries exhibited good storage recoveries. Sample storage ranged from 288 to 328 days prior to analysis. The sample stored for 328 days was a field fortified sample. Therefore, field fortification recoveries demonstrated storage stability of the active ingredient from sample collection through sample analysis.

II. RESULTS AND CALCULATIONS:

A. EXPOSURE CALCULATIONS:

Air samples were analyzed in sets which typically included one concurrent control sample, one or two concurrent recovery samples, and field samples. Overall, a total of 126 sample analyses were performed. The quality control sample reeoveries were reported above. There were no detectable levels of the active ingredient (chlorfenapyr) found in any of the field samples collected during and after application at all four sites. The field fortification recoveries demonstrated good storage stability of ehlorfenapyr for the full length of storage.

III. DISCUSSION

A. LIMITATIONS OF THE STUDY:

This study met most of the Series 875.2500 Guidelines (see Appendix A). The following issues of coneern are noted:

- The study did not result in any useable data from any of the four test sites. Detectable levels of chlorfenapyr were not detected in any of the field air samples.
- Monitoring should have been conducted before residues dissipated beyond the limit of quantification. Although sampling occurred while the application was in progress and immediately after the application, detectable chlorfenapyr was not found.
- According to the guidelines, studies should be conducted under different geographic/climatologic sites. For this study, all four houses were in the same geographic region (Frederick, Maryland).
- Inhalation monitoring techniques, this case stationary air monitoring, should contain sufficient samples to characterize the likely range of possible exposure concentrations. Only three samples per house were collected per sampling event, but none of the three samples contained detectable concentrations of chlorfenapyr.
- Validated analytical methods of sufficient sensitivity are needed. Method validation information supporting sufficient sensitivity was not provided in the Study Report. The linear range of the GC/NICIMS was not provided, but the LOQ was (0.18 µg).
- Information on recovery samples must be included in the study report. A complete set of field recoveries should consist of at least one blank control sample and three or more each of a low-level and high-level fortification. These fortifications should be in the range of anticipated residue levels in the field study. For this study, field fortification recovery data were provided in the study report, with one blank control per fortification sample. However, there was only one fortification level. This fortification level was ten times the LOQ. A fortification level of the LOQ should have been done as well, since there were no detectable levels of chlorfenapyr in the samples. The field fortification samples were said to support storage stability, but there were no low level fortification samples to determine how stable low levels of chlorfenapyr are.
- Particulate levels should be monitored along with vapor phase concentrations unless adequate justification for not doing so is provided. A justification for not monitoring both particulate and vapor phase concentrations of chlofenapyr was not provided in either the study protocol or the study report.

B. CONCLUSIONS:

Chlorfenapyr residues were not detected in any of the air monitoring samples collected at any of the four residences. The LOQ was 0.18 µg or 0.5 ng/L air filtered for 6 hours at 1 Lpm. The quality control samples supported good field and laboratory techniques as well as stability of the active ingredient in storage for up to 328 days. However, the field fortification samples were only prepared at ten times the LOQ (1.8 µg). Field fortification samples should also have been prepared at the LOQ to demonstrate the stability of the active ingredient at low level concentrations.

Name:
Evaluator
Occupational Exposure Assessment Section

Date

Name:
Peer Reviewer
Occupational Exposure Assessment Section

Date

Name:
Head,
Occupational Exposure Assessment Section

Date

APPENDIX A

Compliance Checklist for "Determination of Indoor Air Concentrations of Chlorfenapyr after Application of PHANTOM 2SC Termiticide-Insecticide Applied as a Termiticide Treatment to Basement and Crawl Space Construction Housing"

COMPLIANCE CHECKLIST

Compliance with OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group B: Postapplication Exposure Monitoring Test Guidelines, 875.2500, Inhalation Exposure Monitoring, is critical. The itemized checklist below describes compliance with the major technical aspects of OPPTS 875.2500.

- *The test substance must be the typical end use product of the active ingredient.* This criterion was met.

- *The production of metabolites, breakdown products, or the presence of contaminants of potential toxicologic concern, should be considered on a case-by-case basis.* There were no metabolites or breakdown products of concern with this test product.

- *Applications should occur at the time of season that the end-use product is normally applied to achieve intended pest control.* This criterion was met. The application was made by a licensed professional according to normal procedures during the month of December.

- *Initiating testing immediately before a precipitation event should be avoided.* This criterion is not applicable because applications were made at indoor locations.

- *The end use product should be applied by the application method recommended for the crop. Information that verifies that the application equipment (e.g., sprayer) was properly calibrated should be included.* These criteria were met. The application was done by a licensed professional as per normal procedures and the sprayer used was calibrated prior to use in the study. Results from the calibration were provided in the study report.

- *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate is more appropriate in certain cases.* This criterion was met. The application rate was provided and it was the maximum label application rate.

- *If multiple applications are made, the minimum allowable interval between applications should be used.* This criterion does not apply to this study. Only one application was made at each of the four houses.

- *A sufficient number of replicates should be generated to address the exposure issues associated with each population of interest. In general, the study should include a minimum of 15 replicates per activity, distributed as follows: 5 replicates (i.e., individuals) on each of 3 monitoring periods (i.e., "n" days after application).* This criterion was met. One sample was collected from three areas within each house during each sampling event (except for the application sampling event where basement and crawl space samples were not collected). There were 3 samples per house per sampling event and 12 samples total per sampling event (including all 4 houses). There were 4 monitoring periods resulting in 48 samples collected after the application.

- *The monitoring period should be of sufficient duration to result in reasonable detectability on dosimeters. Monitoring should be conducted before residues have dissipated beyond the limit of quantification. Baseline samples should be collected before the exposure activity commences.* This criterion was not met. Residues were not detectable on any of the air sampling tubes collected on any of the sampling days. This included the day of application.

- *Activities monitored must be clearly defined and representative of typical practice.* This criterion does not apply. Stationary air monitoring samplers were used to collect samples in this study.

- *Inhalation exposure studies must be carried out concurrently with dermal exposure and transferable residue studies.* This criterion is not applicable. This study was conducted to determine air concentrations of chlorfenapyr.

- *The selected sites and seasonal timing of monitoring must be appropriate to the activity.* The selected sites and timing of monitoring were appropriate to the activity performed in the study (application).

- *Studies should be conducted under different geographic/climatologic sites.* This criterion was not met. All four houses were in the same geographic region (Frederick, Maryland).

- *Inhalation monitoring techniques area (i.e., stationary) and/or personal monitoring) should contain sufficient samples to characterize the likely range of possible exposure concentrations, and to ensure that the reentry scenario can be adequately addressed.* It is not known if this criterion was met. Only three samples per house were collected per sampling event, but none of the three samples contained detectable concentrations of chlorfenapyr.

- *Particulate levels should be monitored along with vapor phase concentrations unless adequate justification for not doing so is provided.* This criterion was not met. A justification for not monitoring both particulate and vapor phase concentrations of chlorfenapyr was not provided in either the study protocol or the study report.

- *Retention and breakthrough studies should be performed under conditions similar to those anticipated in the field phase of the study.* This criterion was not met. Formal retention and breakthrough studies were not performed prior to this study. The study report states that the field fortification recovery results supports that breakthrough did not occur.

- *The sampling technique used should be appropriate, given the expected exposure scenario (e.g., the use of personal sampling pumps and sampling times consisting of filter cassettes and resin tubes or polyurethane foam filters is preferred; where personal sampling is not appropriate, stationary monitoring may be conducted.)* This criterion was met. The sampling technique used (stationary air monitoring equipped with XAD-2 air filters) was appropriate for this type of study.

- *Personal sampling pumps should be clipped to the collar in the breathing zone of the test subject.* This criterion does not apply to this study.

- *Stationary samples should be collected from the center of treated fields and from at least 4 other locations, preferably at the cardinal compost points from the center location.* This criterion was not met. Only 3 indoor locations were used to collect air samples. One air monitoring pump was placed in the basement or crawl space of each house where the applications took place. Whether or not these were placed in the center of the treated area is not known.

- *Indoor sampling strategies should be designed based on the nature of the exposure scenario and building type. Samples should be collected at heights representing the breathing zones of the exposed populations (e.g., 18 inches for children; 48 inches for adults).* These criteria were met. Air samplers were placed in rooms most commonly used within each residence (i.e., kitchen, family room). Air sampling tubes were placed approximately 36 inches above the floor, except for the sampler in House 3 crawl space which was approximately 12 inches above the floor due to height limitations).

- *The duration of the sampling interval and air flow rates should be maximized within the appropriate flow rate range to increase the potential for capturing enough residue to be quantifiable.* It is not certain whether or not this criterion was met (as far as the duration of sampling interval is concerned). The sampling intervals lasted 6 hours with pump flow rates of 1 Lpm. There were no detectable levels of chlorfenapyr in the field samples. It is not certain if quantifiable levels would have been detected if the sampling interval lasted 12 hours or more.
- *Air flow rates should be recorded at the initiation and termination of the monitoring period, with the average being used in all calculations.* This criterion was met.

- *Samples should be stored in a manner that will minimize deterioration and loss of analytes between collection and analyses. Information of storage stability should be provided.* These criteria were met.

- *Validated analytical methods of sufficient sensitivity are needed. Information on method efficiency (residue recovery) and limit of quantification (LOQ) should be provided.* This criterion was not met. Method validation information was not provided supporting sufficient sensitivity. The linear range of the GC/NICIMS was not provided, but the LOQ was (0.18 µg).

- *Information on recovery samples must be included in the study report. A complete set of field recoveries should consist of at least one blank control sample and three or more each of a low-level and high-level fortification. These fortifications should be in the range of anticipated residue levels in the field study.* These criteria were partially met. Field fortification recovery data were provided in the study report. There was one blank control per fortification sample. However, there was only one fortification level. This fortification level was ten times the LOQ. A fortification at the LOQ should have been done as well, since there were no detectable levels of chlorfenapyr in the samples. The field fortifications samples were said to support storage stability, but there were no low level fortification samples.

- *Raw residue data must be corrected if appropriate recovery values are less than 90 percent.* This criterion did not apply. There were no detectable levels of chlorfenapyr found in the air samples.

- *Residues should be reported as µg pesticide active ingredient per sample and as an airborne concentration ($\mu g/m^3$). Distributional data should be reported, to the extent possible.* This criterion was not applicable due to the results of the study.

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Chemical:	**1H-Pyrrole-3-carbonitrile, 4-bromo-2-(4-**
PC Code:	**129093**
HED File Code	**12000 Exposure Reviews**
Memo Date:	**11/26/2001**
File ID:	**DPD266948**
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