MEMORANDUM

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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 x 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.