Department of Pesticide Regulation

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M E M O R A N D U M

TO: Denise Webster, Senior Pesticide Use Specialist **HSM-03026**

FROM: Worker Health and Safety Branch

DATE: September 30, 2003

SUBJECT: PESTICIDE DATA EVALUATION

PRODUCT NAME	: Vikane Gas Fumigant
ACTIVE INGREDIENT(S)	: Sulfuryl Fluoride
I.D. NUMBER	: SBRA 201306 E
DOCUMENT NUMBER	: 50223-0061 (parts 1 and 2)
EPA REGISTRATION NO.	: 62719-4
COMPANY NAME	: Dow AgroSciences

SUMMARY OF REGISTRATION REQUEST:

The registrant has submitted an air monitoring study to evaluate bystander exposure and risk potential associated with residential structural fumigation with Vikane Gas Fumigant (active ingredient: sulfuryl fluoride). The Environmental Monitoring Branch has reviewed the study and found the data acceptable. The Pesticide Registration Branch has requested Worker Health and Safety (WHS) to also evaluate the data and comment. Since WHS is currently developing the exposure assessment for sulfuryl fluoride, the air monitoring data provided in this submission will be incorporated into the exposure assessment document.

Study Overview

Briefly, air monitoring was conducted within and surrounding two homes during the application, aeration, and postclearance phases of a fumigation performed at a target dose rate of 16 g/m^3 (16 oz/1000 ft^3, i.e., 2x termite rate if 70°F, 20-hour exposure and 12-hour half-loss time). The total duration of the monitoring was 48 hours from the time of fumigant introduction, and the sampling intervals ranged from 1-8 hours. Two replicate fumigations (24-hour exposure period) were performed at one unfurnished home in Rancho Cordova, CA (Sacramento County) in May 1999 according to current California application and aeration (TRAP, Tarpaulin Removal and Aeration Plan) procedures. Five replicate fumigations (20-hour exposure period) were performed at one furnished home in Maxwell, CA (Colusa County) in September 2000, however, a modified aeration procedure, "Stack" plan, was used. The main difference between the TRAP and Stack plan was the method of active aeration and the timing of tarpaulin removal. The TRAP involved tarpaulin removal after 10 minutes of active ventilation through a plastic duct (secured at roof line) followed by approximately 60 minutes of active aeration. The home was then closed until the following morning at which time it was tested for clearance (i.e., sulfuryl fluoride level not greater than 5 ppm). The Stack plan involved 12 hours of active ventilation

through an exhaust stack (unspecified) with the tarpaulin in place except for a small opening on the side opposite the exhaust fan to allow fresh air under the tarp. After 12 hours, the tarpaulin was removed and the home was tested for clearance.

Method Validation

In 1995, Dow submitted a re-validation of their air monitoring method HEH2.12-38-26(6) (Huff and Murphy, 1995). The limit of quantitation (LOQ) was reported to be 2 µg sulfuryl fluoride with an average recovery of 66.1% for loading of 10-1,000 µg sulfuryl fluoride and flow rate of 100 ml/minute (24 L maximum volume). Furthermore, the authors recommended that a recovery of 66% be used to correct all monitoring data.

According to the analytical method provided in Appendix E of the present study, charcoal tubes were fortified with 14.6-1,003 or 3.5-1,000 µg/tube sulfuryl fluoride resulting in average recoveries of 86 or 83% for phase one or phase two, respectively, at a flow rate of 100-150 ml/minute for approximately 10 seconds. This recovery may have been greater than that reported by Huff and Murphy (1995) since the sampling interval was shorter (10 second vs 0.25-4 hours, respectively). The calculated limit of detection (LOD) and LOQ used for both phases of the present study were 1.78 and 5.94 µg sulfuryl fluoride, respectively, after subtracting background (i.e., control tube) values. Data were reported as nondetectable if less than the LOD after correction for reagent blank and average recovery. Samples with nondetectable levels of sulfuryl fluoride were reportedly assigned a value of one-half the LOD when used to determine a time interval average air concentration. However, protocol deviation #2 (July 20, 1999) for phase one noted that the level at which samples were nondetectable or quantifiable were higher than the 1.78 µg value due to a change in the laboratory fortified standards used in determining the LOD and LOQ. Yet, it appears that an LOD of 1.78 µg and LOQ of 5.94 µg sulfuryl fluoride were used in reporting phase one data found in Appendix III of Appendix D.

One control (0 µg sulfuryl fluoride added to tubes) and one reagent blank were assayed along with each batch of field samples (grouped by replicate, period, and tube section). In phase one, the amount of sulfuryl fluoride detected in controls and reagent blanks ranged from 2.10-7.00 µg and 1.99-6.39 µg, respectively. In phase two, the amount of sulfuryl fluoride detected in controls and reagent blanks ranged from 1.16-4.99 µg and 0.97-4.62 µg, respectively. The reported values of sulfuryl fluoride found in field samples, as well as field spikes and travel spikes, provided in the study summary (Appendix D) were calculated by subtracting a batch-specific reagent blank from the raw sample value, then adjusting for the average analytical recovery estimated for that phase. Although the control value would better reflect the background sulfuryl fluoride associated with the sampling matrix, subtraction of the reagent blank rather than the control probably has not resulted in a significant difference in sulfuryl fluoride levels reported for field samples.

The present study reported field and travel fortified samples (spikes), but these data were not used to correct field samples. The travel and field spikes were prepared off-site (Minnesota) and shipped to the field (California) to be used in estimating potential loss of sample due to field

conditions and transportation. Since these spikes were not exposed to the same conditions as the field samples, i.e., prepared, shipped and stored prior to the actual field sampling, these spikes do not adequately reflect potential loss of sulfuryl fluoride in the field. Therefore, it is recommended that recoveries derived from these spikes not be used in correcting field samples.

Field Sample Analysis

Although charcoal collection tubes (SKC 1 g Anasorb CSC tubes) were separated into an 800 mg front section for gas trapping and a 200 mg back section to detect breakthrough of the gas, back sections were not analyzed for all samples collected. At the discretion of the study supervisor, back sections were only analyzed for certain samples collected during either the first 4 hours of the fumigation (period 1, 4-hour sampling) and the first 1.5-2 hours of aeration (period 7, 1.5-2-hour sampling) in phase one, or during the first 4 hours of aeration (periods 4-7, 1-hour samplings) in phase two. Of the 128 each front and back sections analyzed for periods 1 and 7 in phase one, 44% of front and 22% of back sections had detectable levels of sulfuryl fluoride. Of the 480 front and 400 back sections analyzed for periods 4-7 in phase 2, 35% of front and 16% of back sections analyzed had detectable levels of sulfuryl fluoride, and 6 of back sections were lost ("lab accident"). Generally the amount of sulfuryl fluoride detected in back sections was low. However, there were some instances of back sections having detectable levels of sulfuryl fluoride and their counterpart front sections having nondetectable levels, and some back sections having greater values than their front counterparts. Although the present study concluded that no breakthrough occurred, breakthrough did occur and I would recommend that WHS correct for breakthrough if the present data is used in estimating bystander exposure.

As previously mentioned, reported values for field samples were corrected for a reagent blank and average analytical recovery. However, phase one sulfuryl fluoride values (µg/tube) reported in Appendix B (TWA air monitoring data) and Appendix D (analytical summary) are incongruent. For example, 27.17 µg and 3.81 µg sulfuryl fluoride were reported for front and back sections, respectively, for sample #27631601 (phase one, house 1, period 1, station 5-A) in Appendix D (Appendix III), however, 28.58 µg/tube was reported in Appendix B (Table B-1). The source of the difference in the reported values is not clear.

For phase two data reporting, a value of one-half the LOD was not applied to back sections when reporting the quantity of sulfuryl fluoride per tube (Table B-2 in Appendix B). Only back sections with quantities above the LOD were added to the front section values (Table 4 in Appendix D) in reporting the amount of sulfuryl fluoride per tube in Appendix B (Table B-2).

Study Protocol

The original protocol evaluated by DPR proposed a 2-phase study in accordance with California fumigation practices, with phase one being a pilot to determine the sampling intervals and the distances to place air sampling devices to be used in phase two (definitive phase) (Dow AgroSciences LLC, 1999). The completed study under review cites this protocol with amendments and deviations (Wright *et al*., 2003 Appendix A). Following phase one, the sampling intervals and distances to be used in phase 2 were outlined in amendment 4 (September 1, 2000). In addition, amendment 4 changed the aeration procedure to an

unspecified stack plan/active aeration, rather than the TRAP used in phase one. The TRAP had been developed by the Department of Pesticide Regulation's (DPR) WHS Branch in cooperation with the Pest Control Operators of California and was accepted by DPR as provided for in Title 3 of the California Code of Regulations Section 6780 (c) (Gibbons, 1995). Since it reflects current fumigation industry practice in California, phase one data could be used to estimate bystander exposure potential during all fumigation stages. However, phase one only provides 2 replicates which would reduce confidence in any exposure estimates based upon it. Phase two provides 5 replicates and data associated with the fumigant introduction and exposure period (fumigant application stage) reflect California practices and could be used in estimating bystander exposure during this stage. However, since the phase two aeration procedure differs from current California industry practice, it would not be appropriate to apply this data in estimating bystander exposure during the Stack plan aeration period. Also, it would not be appropriate to compare exposure from the TRAP and Stack methods since different houses were used, and since phase one only has 2 replicates.

The fumigant application rate used in both phases of the study are approximately 1/5 the maximum rate, potential sulfuryl fluoride air concentrations are likely to be much greater than those detected in the present study. Thus, it may be necessary to multiply the exposure estimates by 5 in order to represent bystanders to a fumigation performed at the maximum label rate (e.g., fumigation for powder post beetles rather than termites).

Summary

Supporting the need to evaluate bystander exposure associated with structural fumigations, both phases of the present study report detectable sulfuryl fluoride in the air, up to 50 feet, surrounding structures during the application and aeration phases of a tarpaulin fumigation. Before using the present data to estimate bystander exposures, a few caveats should be noted. First, the application rate used in the present study is approximately one-fifth the maximum application rate, therefore, the reported sulfuryl fluoride air levels may underestimate levels associated with maximum rate applications. Also, the present study reports an analytical recovery of 83-86% compared to a 66% reported in Dow's 1995 method validation (Huff and Murphy, 1995). The difference between the present and 1995 recoveries may be due differences in the sampling intervals (10 second vs. 0.25-4 hours, respectively). If the actual recovery is less than 83-86%, the present values may underestimate the sulfuryl fluoride air levels. Futhermore, the reported sulfuryl fluoride values do not completely account for breakthrough which may also underestimate levels. Although an explanation should be provided, the discrepancy between some phase one values reported in Appendix B and Appendix D is not a concern since phase one data cannot be used for reliable exposure estimates given only 2 replicates.

Phase one of the study (2 replicates) was performed according to current California sulfuryl fluoride fumigation practices which include aeration by the TRAP method (tarpaulin removal after 10 minute ventilation, followed by 50 minutes active aeration, and 5-7 hours of passive aeration before testing for clearance). TRAP had been developed by WHS in cooperation with the Pest Control Operators of California and was accepted by DPR as provided for in Title 3 of the California Code of Regulations Section 6780 (c) (Gibbons, 1995). Although the 2 replicates

from phase one are not sufficient to adequately calculate exposure, they may provide a qualitative estimate of bystander exposure during aeration given these are the only ambient air data available for the TRAP method.

Phase two of the study (5 replicates) employed an alternate aeration procedure, Stack plan, which is not currently used in California. The Stack plan utilizes a 12-hour active aeration prior to removing the tarpaulin and clearance. Bystander exposure during the application stage of a fumigation may be estimated with phase two data from periods 1-3. Although not reflective of current bystander exposure potential during aeration, phase two data from periods 4-7 may be used to estimate exposure during the Stack aeration procedure. Such estimates may be useful in the event that bystander exposures during TRAP need to be mitigated.

In conclusion, the present study does not adequately provide data for estimating exposure during the aeration stage according to current California practices (TRAP). In addition, the current study does not provide sufficient data to compare exposures from the two different aeration methods used. However, sulfuryl fluoride air levels appear to dissipate more quickly using the TRAP method, with no detectable sulfuryl fluoride after the first 1.5-2 hours of aeration (Period 8-13). Following the Stack aeration method, some outdoor air samples had detectable sulfuryl fluoride levels even after clearance (>32 hours (period 9); i.e., house 1 period 10; house 2 period 11; house 4 period 11).

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