



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

NOV 26 1991

MEMORANDUM

SUBJECT: Product Amendment Action for Sulfuryl Fluoride Fumigant
(Vikane)

TO: Esther Saito, Chief
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Please find the OREB review of

HED Project #: 1-2269

RD or SRRD Record #: _____

Caswell #: 816-A

Date Received: 9/17/91

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1.0 INTRODUCTION

DowElanco requested an amendment for their Sulfuryl Fluoride (SF) product EPA Reg No. 62719-4 (VIKANE). The amendment was to alter (update) their aeration procedures for fumigated houses. The request was made after the company discovered that their current procedures may not have been adequate to assure that indoor residues did not exceed 5 ppm of SF. A search of the SF file revealed that the protocol for the following studies was not evaluated or approved.

Data submitted in support of the label amendment include:

- Indoor Airborne Residues to Methyl Bromide and Sulfuryl Fluoride in Fumigated Houses Following Aeration, guidelines reference number 133-4, MRID # 418177-01.
- Post Fumigation Fate of Sulfuryl Fluoride: Desorption From Structural Commodities and Transient and Permanent Residues in Protected and Exposed Foodstuffs, guidelines reference numbers 133-3/4, MRID #403332-01 Desorption From Structural Commodities.

2.0 CONCLUSIONS

The data submitted support the label modification requested in the Application for Amendment submitted on March 7, 1991 for new aeration procedures. The data however, do not satisfy the requirements identified in the Registration Standard in that degradation products and duration of residues on household surfaces and materials were not identified. The data regarding the residues in/on food commodities protected by plastic wrap should be reviewed by Chemistry Branch I.

3.0 DISCUSSION

AERATION PROCEDURES

Study MRID # 418177-01, "Indoor Airborne ResiduesIn Fumigated Houses Following Aeration" indicate that SF concentrations in houses do increase after the house has been aerated and closed. After aeration, concentrations in closed houses raised during the first 30-45 minutes, stabilized and then declined with time. The following chart depicts the concentrations of SF after aeration as well as the time it takes for concentrations to build. The concentrations listed represent the averages and highest concentration for 10 houses fumigated at 16 g/m³ (ca 8640 ppm).

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The registrant's analysis and summary of the data indicated that concentrations did not increase after the first 30 minutes of closure. The composite data is presented in graph form in Figure 1. It indicates that average and maximum concentrations increased for the first 60 minutes and then decreased.

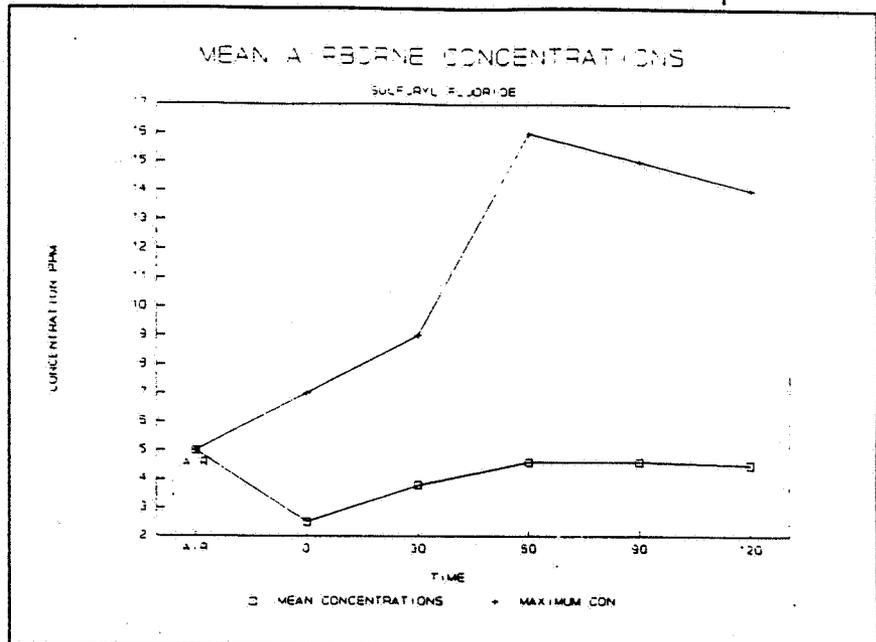


Figure 1: Sulfuryl Fluoride concentrations in 10 homes. Data expressed in ppm.

The new aeration procedures require sequential monitoring that would extend past 40 minutes of closure to detect rising concentrations of SF in a fumigated and aerated house. Rising concentrations require that either additional monitoring or further aeration be done to assure that SF concentrations do not exceed 5 ppm.

There is still one disturbing aspect of the aeration procedure changes. The studies presented to support the label changes indicate that the house "air handling system" was energized to help "air" the house while the windows and doors were open. The new label changes do not contain that instruction. Since the air system in a house is a potential sink for concentrations of SF, it is logical that it should be energized to "air" it out also. Failure to do so could introduce additional SF into the rooms of a closed house. Instructions for energizing the air handling system may currently be in the supplemental product labeling (not available to this reviewer). If it was important enough to be a part of the study protocol, it should probably be a part of the main label instructions. The position and wording of this label statement will be left to the product manager and the registrant.

As part of the Registration Standard data requirements, the registrants were to provide data that identified and quantified the nature of residues which may be released in the air spaces of habitable structures from the treated surfaces and non-food articles. The study "Post Fumigation Fate of Sulfuryl Fluoride:...., MRID# 403332-01 was submitted to fulfill that requirement. Chamber studies with various types of materials were conducted and the air in the "head space" was analyzed for SF and its degradation products. For all materials tested, the only volatile components detected in the head spaces were that of Parent SF and constituents of ambient air. No degradation products of SF were found in any of the head spaces above the commodities tested.

Although this study was not a data requirement of OREB, the data was interesting in that it suggested that dermal and oral exposures need to be evaluated.

The following TABLE represent the quantities of SF desorbed from a select group of commodities after being exposed for 20 hour to 36 mg/l and 360 mg/l respectively. Various materials were exposed in chambers, aerated and then the chambers were resealed. The results are given in ppb with the limit of sensitivity = 1.0 ppb.

HEADSPACE GASES: SF FUMIGATED AT 36 mg/l for 20 hours. Data expressed in ppb.						
COMMODITY	2 HRS	8 HRS	26 HRS	120 HRS	480 HRS	960 HRS
POLYESTER	9174	3814	2995	620	44	7
NIPPLE	20256	8007	8	2	1	ND
TOY (PLASTIC)	2204	930	558	89	8	1
WOOD	14496	6179	2369	82	ND	ND
POLY- STYRENE	975347	531889	267237	48129	390	5

HEADSPACE GASES: SF FUMIGATED AT 360 mg/l for 20 hrs. Data expressed in ppb.						
COMMODITY	2 HRS	8 HRS	26 HRS	120 HRS	480 HRS	960 HRS
POLYESTER	93350	58757	34173	7302	481	92
NIPPLE	218829	99230	15216	9	ND	ND
TOY (PLASTIC)	23110	15717	7048	1124	85	14
WOOD	169790	89146	32784	1897	2	ND
POLY- STYRENE	9742060	4936716	2216094	233239	2788	15

NOTE: OTHER MATERIALS WERE TESTED. HOWEVER, THE MATERIALS THAT ADSORBED AND DESORBED THE MOST GAS ARE LISTED IN THE ABOVE CHART.

The data indicate that SF is desorbed for up to 40 days and that there are no degradates present. These data, in conjunction with the previous study suggests that fumigated homes may contain low levels (in the ppb level) of SF for many days (up to 40) after fumigation. However, one must consider that the residues will be in the ppb range. Houses fumigated at normal levels (data shows 10X and 100X normal levels) should be virtually free of detectable residues of SF gas after 40 days. However, the data are not available identifying surface residues.

The registration standard requested data to identify, quantify and give residence times for residues on surfaces inside treated houses. The data on the infant nipples (latex), plastic toys and polystyrene are intriguing and presents the question of what kind of oral doses infants and other occupants receive from the dishes and flatware used every day. Are residues removed from these surfaces with normal washing? Do these residues present a significant dietary intake to worry about? When the additional data arrive identifying the type and quantity of residues on household articles, these questions should be answered. In addition to residues on textiles requested in the standard, residues on surfaces that are expected to come into contact with the mouth, should be identified.

cc: Circulation
Correspondance File
Chemistry Branch I
Chemical File