078003

Shaughnessy #: 078003
Date out of EAB: January 16, 1987
Signature: _____

To: Walter Francis and Jeff Kempter
Product Manager #32
Registration Division (TS-767C)

From: Joseph C. Reinert, Chief
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached please find the EAB review of:

Reg./File No.: 464-236

Chemical: Sulfuryl fluoride

Type Product: fumigant

Product Name: VIKANE

Company Name: Dow Chemical Co.

Submission Purpose: Protocol Review

Date In: 6-13-86 ACTION CODE: 661

Date Completed: 1-16-87 EAB # 60679

Monitoring Requested: _____ _____ _____

Monitoring Voluntarily Done _____ _____ _____

Deferrals To:

_____ Ecological Effects Branch

X Residue Chemistry Branch

_____ Toxicology Branch

_____ Benefits and Use Division

Introduction

Dow Chemical Co. has submitted a revised exposure study protocol (letter of R. Bischoff, 6/9/86 and encl.) based upon comments from our review of 1/22/86 (memo. of Anne Keller). The original protocol had been submitted in response to the reregistration guidance document for sulfuryl fluoride.

Discussion

The registrant proposes to conduct residue analyses of food, medicinal and non-food (including clothing and construction materials) items subjected to sulfuryl fluoride fumigation in a closed chamber. At specified time intervals after aeration, the non-food items would be analyzed by modified headspace analysis. Specifically, the aerated items would be stored in an airtight chamber for 2 hours after which the air would be measured for sulfuryl fluoride. These studies would continue on each item up to 40 days after aeration until the headspace residues were no longer detectable.

EAB is concerned with the volatilized residue from structural fumigation as specifically measured by passive dosimetry (personal monitoring) techniques. These are delineated in the Pesticide Assessment Guidelines Subdivision U "Applicator Exposure Monitoring" available through the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (703-587-4650). The data must include an exposure monitoring study and an identification and description of work activities and use-related information.

Conclusions

1. The fixed location chamber studies described by the registrant can not be used directly for human exposure assessment purposes. A personal monitoring study is required if a risk assessment for sulfuryl fluoride is required.

2. Finally, EAB does not require the residue studies on food or non-food items. We defer to RCB for the need for this type of data as well as its evaluation.

Allan J. Reiter

Allan J. Reiter, Ph.D.
Chemist, Exposure Assessment Branch

* * *

Confidential Business Information—
Does Not Contain National Security Info. (E.O. 12065)

16426
6/13/86

CHEMICAL NAME: Sulfuryl Fluoride

(RD PROVIDE SHAUGHNESSY NO.) 078003

(HED/BUD/TSS COMPLETE)

Identifying Number	Action Code	Reference Number	Record Number	Study Guideline or Narrative Description	Reg. Std. Review Submission Criteria (SEE BELOW)	Accession Number	Indicate with an (X) any of the listed submissions which are not studies as defined by the study guidelines
464-236	661	3	175,326	Exposure Protocol	3	None	

PRODUCT MANAGER (PM) or REVIEW MANAGER (RM) AND NUMBER: Jeff Kempter, Acting PM-32 557-3964

PM/RM TEAM MEMBER AND NUMBER: Walter C. Francis 557-3964

DATE RECEIVED (EPA): 6-10-86

RD BRANCH CHIEF INITIALS:

CHECK APPLICABLE BOX:

- ☐ Adverse 6(a)(2) Data (405,406)
- ☐ Suspect Data (415,416)
- ☐ IBT Data (485,486)
- ☐ Product Specific Data (Reregistration) (655,656)
- ☒ Generic Data (Reregistration) (660,661)
- ☐ Special Review Data (870,871)

AH

NUMBER OF INDIVIDUAL STUDIES SUBMITTED: 1

HAVE ANY OF THE ABOVE STUDIES (in whole or in part) BEEN PREVIOUSLY SUBMITTED FOR REVIEW? (circle: (yes) or no) If yes, please identify the study(ies): Exposure Protocol

RELATED ACTIONS:

INSTRUCTIONS: Attached is an exposure study protocol revised in accordance with the comments of Anne R. Keller dated 1-22-86. Please review as soon as possible in order that the applicant can develop the data in time to meet the 12-31-86 due date imposed by the Sulfuryl Fluoride Registration Standard. For additional information, please contact Walter C. Francis at 557-3964.

TO BE COMPLETED BY RSERB

DATE SENT TO HED/BUD/TSS: 6-13-86

PRIORITY NUMBER: 5D

PROJECTED RETURN DATE: 7-14-86

DATE RETURNED TO RD (HED/BUD/TSS PROVIDE):

REVIEWS SENT TO:

HED: ☐/SIS ☐/TB ☒/RCB ☒/EAB ☐/EEB RD: ☐/TSS BUD: ☐/EAB ☐/SSB

TO:	TYPE OF REVIEW	NUMBER OF ACTIONS: Reregistration	Special Review	Other
	Toxicology			
	Ecological Effects			
	Residue Chemistry			
X	Exposure Assessment	1		
	Product Chemistry			
	Efficacy			
	Precautionary Labeling/Acute Tox.			
	Science Support			
	Economic Analysis			

FOR DATA SUBMITTED UNDER A REGISTRATION STANDARD: Review Submission Criteria

Policy Note #31

1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria

2 = data of particular concern

3 = data necessary to determine tiered testing requirements

NOTE TO TSS: Return 1 Copy To RSERB

INCLUDE AN ORIGINAL AND FOUR (4) COPIES OF THIS COMPLETED FORM

DOW CHEMICAL U.S.A

POST OFFICE BOX 1706
MIDLAND, MICHIGAN 48640

9008 Building
June 9, 1986

Mr. A. E. Castillo
Registration Division
U. S. Environmental Protection Agency
Room 244, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Castillo:

SUBJECT: Sulfuryl Fluoride Reregistration
Exposure Study Protocol

Enclosed for consideration by the EPA are three copies of an exposure study protocol that has been revised based on comments received on March 18 and April 21, 1986 from the Agency's Environmental Assessment Branch and Residue Chemistry Branch, respectively. It is pertinent to note that some of the items listed for analysis have been changed because it was either repetitive in nature or posed a difficult analytical problem because of its content i.e., high salt content that would interfere with ion detection of degradation products.

Because we are anxious to start the exposure study to meet the EPA's timeline requirement of December 31, 1986, we are requesting an expedited review of the enclosed study protocol. Please insure that if the Agency has any concerns regarding this study that you respond to me either orally or in writing before June 30, 1986. Thanks for your continued assistance on our behalf.

Sincerely,

Robert F. Bischoff

Robert F. Bischoff
Product Registration Manager
Agricultural Products Department

jlm

Enclosures

VIKANE (Sulfuryl fluoride) EAB Review 1/16/87

Page ____ is not included in this copy.

Pages 5 through 25 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

✓ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.