

#### OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

October 23, 2023

Tim McPherson Director of Regulatory Affairs/R&D Douglas Products 1550 East Old 210 Highway Liberty, MO 64068

Dear Mr. McPherson:

The memorandum Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-Entry Mitigation Measures dated June 28, 2023, required label changes to address the potential human health risks of concern from the use of sulfuryl fluoride (SF) at residential sites. The memorandum Amendment to the Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-Entry Mitigation Measures Memorandum, June 2023 dated September 27, 2023, clarified the requirements and the label language in response to registrant and stakeholder comments. The revised labels and requests for amendment of registrations must now be submitted to the Agency (Pesticide Re-evaluation Division) for review by Monday, October 30, 2023.

Since the May 2021 release of the Agency's study on the effectiveness of sulfuryl fluoride clearance devices, *Laboratory Testing of Portable Clearance Devices with Sulfuryl Fluoride Standard*<sup>1</sup>, the Agency has met with Douglas Products on SF-related issues 23 times. In addition, the Agency met with other stakeholders such as state regulators and user groups 12 times to confirm mitigation. The Agency has responded to Douglas Products' concerns regarding the required label language changes including the label drafting/technical error corrections, aeration/clearance device/website related issues, and existing stocks period/implementation of new labels. The Agency even revised mitigation in response to registrant and stakeholder comments provided outside of the official comment period when preparing the June 28, 2023, memorandum.

The Agency also met with Douglas Products since the issuance of the memorandum on June 28, 2023, and has discussed their concerns regarding sulfuryl fluoride internally. On September 27, 2023, the Agency clarified some label language and provided Douglas the response memo: "Response to Comments Submitted by Douglas Products on July 24, 2023, "Sulfuryl Fluoride Revised Mitigation Measures; Outstanding Issues Requiring Attention." In that document, EPA explains its full consideration of the issues raised by Douglas and made adjustments to accommodate those comments where appropriate.

<sup>&</sup>lt;sup>1</sup> Analytical Chemistry Branch (ACB), Biological and Economic Analysis Division (BEAD), Office of Pesticide Programs, 2021.

EPA required sulfuryl fluoride registrants to submit labels incorporating required mitigation by Monday, October 30, 2023. The Agency team conferred with OCSPP Assistant Administrator Michal Freedhoff and Office of Pesticide Programs Director Edward Messina on October 19, 2023, and they concur on the required label changes and the October 30 deadline for label submission.

At this time, EPA believes the best way to mitigate the potential risks associated with these products is to amend the labels as EPA has indicated in the attached, "Final Amended Sulfuryl Fluoride Label Table 10, 23, 2023". If labels for the products identified (Douglas Products, EPA Registration. nos. 1015-78, 1015-80, and Ensystex product, EPA Registration No. 81824-1) are not submitted by Monday, October 30th, 2023, EPA intends to consider whether regulatory or enforcement action may be appropriate.

The "Final Amended Sulfuryl Fluoride Label Table 10.23.2023" which is attached to this document, lists the final requirements for SF labels in response to the OIG audit, that are due on SF labels on October 30, 2023.

## Douglas Comments on October 12, 2023

Responses to the following comments submitted on October 12, 2023, are described here and included in the attached label table. On October 12, EPA received an email from Stephanie Stephens of Exponent regarding Douglas' concerns with EPA's positions. The email listed 3 main topics that the Douglas team wished to discuss further. However, as outlined below, these concerns have already been discussed.

- 1. <u>Alternate proposals for Aeration Procedures 1 and 2</u>: Douglas provided a document to EPA on October 11, 2023, via email from Tim McPherson proposing label language under which an extended 2-hour active aeration (exactly as proposed by EPA) would be the default, but fumigators would have the option to check the structure after 1-hour. If all the rooms were at or below a specified value (4 ppm) after the first hour, then the job could move to the passive aeration phase. If not, then the full two hours would be required.
- 2. <u>Clearances devices</u>: EPA shared updated label language on the clearance devices on October 11, 2023, via email from Moana Appleyard. Douglas expressed concerns regarding the proposed language as it did not include that using a device listed as "Not Effective" on EPA's website would be a violation of FIFRA.
- 3. <u>Continuing education requirements</u>: EPA proposed continuing education requirements in the Agency's memorandum dated September 27, 2023, and EPA has not responded to Douglas' proposed alternate language shared by Tim McPherson via email on October 11. Douglas proposed to modify the language to read: "[a]ttendees must demonstrate knowledge and understanding of the training content consistent with the requirements for obtaining credit for having taken the course of the applicable state continuing education program for pest control operators." EPA proposed "[a]ttendees must demonstrate knowledge and understanding of the training content with a passing grade of 80%."

### EPA's Response to Alternate proposals for Aeration Procedures 1 and 2

EPA met with the Douglas team on August 17, 2023, in response to a letter from Tim McPherson dated July 24, 2023. The EPA's conclusions were communicated during the meeting on August 17, 2023. EPA concluded the data support longer aeration times as the only reliable method to ensure adequate dissipation of SF; therefore, as a risk management decision, the 2-hour active aeration time requirement will be retained.

Per the memorandum *Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-Entry Mitigation Measures* dated June 28, 2023, the Agency determined that revised aeration

procedures are necessary to ensure the safe re-entry into fumigated structures. The concern over the inability to accurately detect SF with existing portable clearance devices led the Agency to require expanding the aeration procedures to ensure that SF has sufficiently dissipated prior to anyone reentering a fumigated structure. Early mitigation based on the OIG report for SF proposed removing Aeration Procedures 1 and 2 and replaced those procedures with the California Aeration Plan (CAP). After receiving comments during the public comment period on the CAP proposals, EPA altered its mitigation proposal and revised it to require extended aeration times (both active and passive) and removed the requirement of keeping tarps on the structure for the entire aeration period. As longer aeration times are the most effective way for SF to disperse, the Agency believes the revised aeration requirements are needed to provide necessary protections for people re-entering fumigated structures. Therefore, the October 11, 2023, proposal is not acceptable to the EPA.

## EPA's Response to Clearance Devices

On September 29, 2023, EPA met with the Douglas team and Ken Kendall from Ensystex. EPA discussed the details of the memorandum *Amendment to the Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-Entry Mitigation Measures Memorandum, June 2023* dated September 27, 2023, and recent comments submitted on the proposed mitigation. Moana Appleyard emailed Douglas Products a proposal stating that "if [the registrants] can submit the language in the next couple of days, and if we can get agreement on that language, the change will not affect the time frame for revised sulfuryl fluoride labels to be submitted to the Agency, with the language listed in the SF Amendment." In response, the Douglas team proposed via email from Tim McPherson on October 3 the following label language:

"Registrants, remove all references to clearance devices being 'approved.' Replace language with the following statement:

'Confirm concentration of sulfuryl fluoride of 1 ppm or less, with a clearance device permitted by [Registrant] for use with [Product] as meeting the Agency's Reliability and Accuracy performance criteria for detection at 1 ppm. Refer to EPA's website at Sulfuryl Fluoride | US EPA (https://www.epa.gov/ingredients-used-pesticide-products/sulfuryl-fluoride) for more information and a list of devices that EPA has determined to be "Effective" and "Not Effective" based on Agency testing. A device listed as "Not Effective" on EPA's website may be used if the device is permitted by [Registrant]."

EPA was concerned about the statement being misbranding and revised the statement to the following, which is included in the attached 10.23.2023, SF label table:

"Registrants, remove all references to clearance devices being 'approved.' Replace language with the following statement:

'Confirm concentration of sulfuryl fluoride of 1ppm or less. Refer to EPA's website at Sulfuryl Fluoride | US EPA (<a href="https://www.epa.gov/ingredients-used-pesticide-products/sulfuryl-fluoride">https://www.epa.gov/ingredients-used-pesticide-products/sulfuryl-fluoride</a>) for more information and a list of effective clearance devices.' "

### Douglas Comments on Agency Review of Clearance Device Data

The following is the Agency response to the October 13, 2023, email from Douglas Products, concerning their comments on the Agency review of their most recent clearance device data, "Douglas Products' Response to Data Evaluation Record for MRID No. 52213401." The MRID is the latest study submitted by Douglas Products on July 10, 2023, evaluating whether the SF-ExplorIR clearance device

meets EPA's Accuracy and Reliability criteria for the effectiveness of such devices. EPA has listed the SF-ExplorIR as "Not Effective" on its website and the recent data submitted by Douglas did not provide additional information sufficient to change this designation. As discussed in the Agency review of MRID, 52213401, and during previous discussions with Douglas, there were several concerns with the study that resulted in it being designated as invalid.<sup>2</sup> Of the concerns with MRID 52213401, the DER outlines the Agency's main issue with the study, which was the lack of a verified standard at 1ppm, as required in the Agency protocol, available at https://www.epa.gov/ingredients-used-pesticideproducts/guidance-sulfuryl-fluoride-clearance-device-testing#submit-protocol. EPA's conclusions on this study were shared with Douglas on October 17, 2023. In that meeting, Douglas Products stated that EPA should conclude, based on the most recent Douglas study (MRID 52213401), as well as their previously study (MRID 51743801), that the SF-ExplorIR meets EPA's Reliability and Accuracy criteria for detecting at the clearance limit of 1 ppm. The Agency reviewed the 10/13/2023 comments from Douglas Products and found they did not address the Agency concerns on the submitted test, including the Agency's main concern regarding the reliability of the laboratory prepared 1 ppm SF standard. The Agency had suggested that an independently prepared or certified SF standard at 1 ppm be used to test the SF-ExplorIR or to verify the laboratory prepared 1 ppm SF standard. The Douglas study did not use independently verified standards and the comments attempted to explain that the diluted standards they used in the study were adequate. The Agency has determined that the 10/13/2023 comments did not provide sufficient evidence to support the argument that the laboratory prepared 1 ppm SF standard is reliable and the SF-ExplorIR is effective at detecting SF at 1 ppm. EPA maintains that the language referring to EPA's website that provides a list of effective clearance devices is required on sulfuryl fluoride labels. Per the memorandum Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-Entry Mitigation Measures dated June 28, 2023, the Agency conducted an assessment of clearance devices to validate their effectiveness in detecting required clearance levels. The EPA's conclusions are published in *Final Report – Laboratory* Testing of Portable Clearance Devices with Sulfuryl Fluoride Standard available in the sulfuryl fluoride public docket. Additionally, these results have been shared in 2 webinars on May 19 and 20, 2021 to registrants, device manufacturers and stakeholders and posted all documentation to the public docket on (date, 2021).

In summary, all references to "approved" clearance devices must be removed from Agency approved labels, whether the devices meet the criteria for effectiveness or not, according to the Agency criteria, as this would represent misbranding. Additionally, none of the data submitted by Douglas Products to date supports the SFExplorIR as effective in measuring the clearance level of 1 ppm.

#### EPA's Response to Continuing Education Requirements

The Agency amended the language for the Registrants Stewardship training requirements under the Initial Training and Annual Recurrent Training, to include a metric for enforcement.

"[a]ttendees must demonstrate knowledge and understanding of the training content with a passing grade consistent with the requirements for obtaining credit for having taken the course of the applicable state continuing education program for pest control operators."

<sup>&</sup>lt;sup>2</sup> Data Evaluation Record of MRID No. 52213401 (2023), SF-ExplorIR 08122023. Analytical Chemistry Branch, Office of Pesticide Programs.

## Aeration Label Language Update

The Agency conferred with representatives from the California Department of Pesticide Regulation (CalDPR) on October 23, 2023, and has revised the aeration reference to the California Aeration Plan (CAP), during a blow open. The following statement is removed from the 10.23.2023 SF label requirement:

"In California, for a structure in which aeration using the California Aeration Plan (CAP) failed during the aeration time specified in Table 2 in CAP (e.g., the tarpaulins blew open, the ducted aeration fan failed, etc.), Aeration Procedure 2 must be conducted using a minimum wait time using the Table X from the initiation of aeration in Step (1)."

Based on the conclusions of all the issues as outlined above, there is no issue in which to meet and discuss and the amended label must include the label changes as outlined in the attached label table, Final Amended Sulfuryl Fluoride Label Table 10.23.2023. Appendix B are due on Monday, October 30, 2023.

Sincerely,

Mary Elissa Reaves, Ph.D.

Director

Pesticide Re-evaluation Division

Office of Pesticide Programs

ENCLOSURE, Appendix B. Required Label Changes for Sulfuryl Fluoride Products – October 23, 2023

cc: Wes Long, CEO, Douglas Products Scott Johnston, Vice President of Operations, Douglas Products Heather Kern, Commercial Leader- Management Division, North America, Douglas Products Stephanie Stephens, Exponent Ken Kendall, Ensystex

# **APPENDIX B. Required Label Changes for Sulfuryl Fluoride Products - October 23, 2023**

Description	October 23, 2023 Label Language for Sulfuryl Fluoride Products for Residential Fumigation	Placement on Label
	End Use Products	
Warning Sign Label Language.  Posting of Fumigated Areas Language is for Residential Fumigants. List includes a baseline of requirements for warning signs. States that currently have requirements for warning signs that include these elements listed here, can maintain those requirements for warning signs. Additional elements imposed by states may also be added for residential structural fumigations.	"The following is a baseline of requirements for warning signs to be posted for fumigations using [Product name]. States that currently have requirements that are comparable to the elements listed here, can maintain those requirements for warning signs. Additional elements imposed by states may also be added to these warning signs.  1. The applicator must post the fumigated areas with warning signs with a white background stating the following:  a. The signal word DANGER/PELIGRO at a minimum height of 2 inches, the SKULL and CROSSBONES symbol at a minimum height of 1 inch, and the statement "Area under fumigation, DO NOT ENTER/NO ENTRE" - all printed in one or more colors contrasting with the white background b. The date of fumigation.  c. Brand name of fumigant used (minimum height ½ inch).  d. Name, address, and telephone number of the applicator, or company performing the fumigation.  2. Information on warning signs must remain legible and visible for the duration of the fumigation and aeration periods.  3. Warning signs must be placed on the structure at or near all doors and entrances.  4. On tented structures, additional warning signs must be placed on the outside of the tarp so that they are clearly visible from all accessible sides, and from any direction from which the site may be approached."	In the Directions for Use under the heading "Posting of Fumigated Areas"
Site-specific Structural Fumigation Log for all end-use products containing directions	"Structural Fumigation Log requirements. The following elements for structural fumigation for each site must be documented.	In the Directions for Use under the heading "Site-Specific Structural Fumigation Log"
for residential uses. Listed elements are a baseline of requirements for fumigation logs. Comparable elements that are currently required under state regulations can be used to	The Site-specific Structural Fumigation Log is intended to ensure a safe and effective fumigation. The certified applicator in charge of fumigation is responsible for verifying that a Fumigation Log must contain, as a minimum, the information listed below. The information followed by a "(B)" below must be documented before the initiation of the fumigation; other information listed below without a "B" must be documented during the fumigation process, if not before. Contracts, site graphs, dose calculation reports,	

Description	October 23, 2023 Label Language for Sulfuryl Fluoride Products for	Placement on Label
Description	Residential Fumigation	Tracement on Laber
satisfy the equivalent requirement of each element on this label.  A residential structure is where people typically live (temporarily or permanently) and sleep, such as single-family residences, mobile homes, apartments, townhouses, condominiums, hotels, motels, assisted care facilities, nursing homes, hospitals, barracks, and dormitories.	Residential Fulligation  Residential Fulligation  Residential Fulligation  for documents prepared for or used during the fumigation can be used as documentation for these Fumigation Log requirements.  Fumigation employees who introduce chloropicrin and sulfuryl fluoride, initiate aeration, and/or conduct final clearance testing must have participated in the registrant's sulfuryl fluoride training, as required by the registrant's stewardship plan.  1. General Information:  • Fumigation company (B) • Fumigation site address (B) • Structure type (B) • Target pest(s) (B)  2. Fumigant introduction:  Dosing calculations:  • Dosage factor • Tarp condition • Under seal type • Seal condition • Wind (mph) • Volume of fumigated space (1000 cubic feet) (B) • Underseal • Temperature • Hours of Exposure  Introduction of chloropicrin and sulfuryl fluoride: • Name, license number, and signature of certified applicator responsible for introduction of chloropicrin and sulfuryl fluoride. • Name, of second trained person(s) and certified applicator responsible for introduction of chloropicrin and sulfuryl fluoride. • Name(s) of second trained person(s) and certified applicator(s) assisting with introduction of chloropicrin introduced and number of introduction sites. • Cylinder serial number(s) of sulfuryl fluoride applied. • Dounds of fumigant applied.	

Description	October 23, 2023 Label Language for Sulfuryl Fluoride Products for	Placement on Label
-	Residential Fumigation	
	<ul> <li>Name, license number, and signature of certified applicator responsible for initiating aeration.</li> <li>Name(s) of certified applicator(s) and second trained person(s) assisting with initiating aeration.</li> <li>Date and time of aeration initiated.</li> <li>Final clearance testing:         <ul> <li>Name, license number, and signature of certified applicator responsible for conducting final clearance testing.</li> <li>Name(s) of certified applicators assisting final clearance testing.</li> <li>Date and time final clearance testing completed.</li> <li>Clearance device model type</li> </ul> </li> <li>Emergency response information: "Get exposed person to fresh air. Call 911 or an ambulance. Keep exposed person warm and at rest. Make sure person can breathe freely. If breathing has stopped, give artificial respiration. Do not put anything in the mouth of an unconscious person."</li> <li>Open Comment field: Provide an open field for additional comments or issues that is not captured in other sections of this Structural Fumigation Log."</li> </ul>	
Product Stewardship Plan reference for residential structural fumigations.  A residential structure is where people typically live (temporarily or permanently) and sleep, such as single-family residences, mobile homes, apartments, townhouses, condominiums, hotels, motels, assisted care facilities, nursing homes, hospitals, barracks, and dormitories.	"[The registrant]'s Product Stewardship Plan that includes EPA's stewardship plan criteria is available at Sulfuryl Fluoride   US EPA. Applicators and distributors of [product name] must participate in [the registrant's] Product Stewardship Plan for residential structural fumigations. This plan is also available at Sulfuryl Fluoride   US EPA for [Product name]. [Product name] must only be used by application personnel who satisfactorily comply with the [product name] Stewardship Plan, including the initial and annual training requirements."	In Directions under heading "[the registrant]'s Product Stewardship Plan

Description	October 23, 2023 Label Language for Sulfuryl Fluoride Products for	Placement on Label
2 escription	Residential Fumigation	
Language Regarding Portable Clearance Devices	Registrants, remove all references to clearance devices being "approved." Replace language with the following statement:  "Confirm concentration of sulfuryl fluoride of 1ppm or less. Refer to EPA's website at Sulfuryl Fluoride   US EPA (https://www.epa.gov/ingredients-used-pesticide-products/sulfuryl-fluoride) for more information and a list of effective clearance devices."	In the Directions for Use under the heading "Aeration and Reentry"
Aeration and Reentry Requirements for residential structures.  A residential structure is where people typically live (temporarily or permanently) and sleep, such as single-family residences, mobile homes, apartments, townhouses, condominiums, hotels, motels, assisted care facilities, nursing homes, hospitals, barracks, and dormitories	Registrants, for residential fumigations, replace the language for Aeration Procedures 1 & 2 with the revised language, which reflects the new aeration times:  "Preparation Section  Prepare for Aeration Procedures 1 and 2 by doing the following:  Open all operable attic doors and accesses and direct a fan into the attic.  Position introduction and circulation fans to provide for air circulation throughout the fumigated space. For example, a circulation fan in the hall could be used to aid air circulating in bedrooms and bathrooms.  Use a minimum of one fan of at least 18 inches in diameter for every 22,500 cubic feet of space to be fumigated.  Select the appropriate procedure based on the fumigation rate:  All structures fumigated at 16 oz/MCF (1,000 cubic feet of gas) or less may be aerated using Aerations Procedures 1 or 2.  All structures fumigated at concentrations greater than 16 oz/MCF must be aerated using Aeration Procedure 2.  Aeration Procedure 1  These steps must be completed in sequence.  Step (1): Aerate structure with all operable windows and doors open, aided by at least one fan (of at least 18 inches in diameter) for every 22,500 cubic feet of fumigated space, for a minimum of 2 hours following the directions in the Preparation section. If the structure has an attached garage, the door between the garage and structure should be open. If the structure has a central air system, turn on only the fan (or blower) for each operational unit. As an alternative, a circulation fan may be placed in front of a	In the Directions for Use under the heading "Aeration and Reentry"

Description	October 23, 2023 Label Language for Sulfuryl Fluoride Products for	Placement on Label
•	Residential Fumigation	
	furnace inlet to blow air into central heating and cooling ducts. Removal of all chloropicrin evaporation containers from the fumigated space during Step (1) will aid in the dissipation of the warning agent from the structure.	
	<b>Step (2):</b> Secure structure and do not allow reentry for a minimum of 12 hours from the start of aeration (first opening of the seal) for residential structures <sup>1</sup> . During this time structures must remain posted with warning signs.	
	Step (3): After the minimum 12-hour waiting period in Step (2), measure the concentration of [Product name] in breathing zones of each room using a clearance device listed on the EPA website at Sulfuryl Fluoride   US EPA. If the concentration of [Product name] is greater than 1 ppm, ventilate structure with operable doors and windows open and confirm concentrations are 1 ppm or less before the structure is reoccupied.	
	In California, for a structure in which aeration using the California Aeration Plan (CAP) failed during the minimum 12-hour aeration time specified in CAP, (e.g., the tarpaulins blew open, the ducted aeration fan failed, etc.), Aeration Procedure 1 or 2 must be conducted as described above using a minimum wait time of 12 hours from the initiation of aeration in Step (1).	
	Aeration Procedure 2 These steps must be completed in sequence. Step (1): Aerate structure with all operable windows and doors open, aided by at least one fan (of at least 18 inches in diameter) for every 22,500 cubic feet of fumigated space, for a minimum of 2 hours following the directions in the Preparation section. If the structure has an attached garage, the door between the garage and structure should be open. If the structure has a central air system, turn on only the fan (or blower) for each operational unit. As an alternative, a circulation fan may be placed in front of a furnace inlet to blow air into central heating and cooling ducts. Removal of all chloropicrin evaporation containers from the fumigated space during Step (1) will aid in the dissipation of the warning agent from the structure.	
	Step (2): Secure the structure and do not allow reentry the minimum number of hours as listed in the Table X. Determining Minimum Hours of Aeration Time Based on Initial Concentration of Sulfuryl Flouride Introduced, from the start of aeration (first opening of the seal) for residential structures. During this time the structure must remain posted with warning signs.	

Description	October 23, 2023 Label Language for Sulfuryl Fluoride Products for Residential Fumigation		Placement on Label
	Step (3): After the minimum waiting period, measure the concentrations of [Product name] in breathing zones of each room using a clearance device listed on the EPA website at Sulfuryl Fluoride   US EPA. If the concentration of [Product name] is greater than 1 ppm, ventilate structure with operable doors and windows open and confirm concentrations are 1 ppm or less before the structure is reoccupied.  Table X. Determining Minimum Hours of Aeration Time Based on Initial Concentration of Sulfuryl fluoride Introduced		
	Initial Concentration of Sulfuryl Fluoride	Minimum Hours of Aeration	
	Introduced (ounces per thousand cubic feet)	Time**	
	Greater than 16 to 32	14	
	Greater than 32 to 48	16	
	Greater than 48 to 64	18	
	Greater than 64 to 96	20	
	Greater than 96 to 112	22	
	Greater than 112	24	
	**When the high ambient temperature for the aeration period is below 40°F at the fumigation site, a minimum of 24 hours of aeration is required.  1 A residential structure is where people typically live (temporarily or permanently) and sleep, such as single-family residences, mobile homes, apartments, townhouses, condominiums, hotels, motels, assisted care facilities, nursing homes, hospitals, barracks, and dormitories."		