



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

November 9, 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*, which was amended on September 27, 2023, required label changes to address the potential human health risks of concern from the use of sulfuryl fluoride (SF) at residential sites. The revised labels were due to the Agency (Pesticide Re-evaluation Division) on **October 30, 2023, and are now considered past due.**

The following are the Agency's responses to the November 1, 2023, email and attachment from Tracy Heinzman on behalf of Douglas Products (Douglas) to Edward Messina and Elissa Reaves, "20231101_Proposal for EPA on Device Language & Label Terms".

1. **Label Component:** The Agency does not support the Douglas proposal to replace "a list of effective" with "concerning" in the label reference to the list of clearance devices on the EPA website. The term effective is related to the performance criteria used in the Agency's assessment of clearance devices and must be retained. Therefore, the label statement requirement remains as listed in the label table below:

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

2. **EPA Website Component:** The Agency does not support Douglas' proposed statement, "The M.A.C 2640 CLIRCheck, FumiSpec-Lo, SF-ExplorIR, or the Interscan GF1900 may be used as clearance devices under labeling for Vikane and Zythor through completion of the current registration review process for sulfuryl fluoride."

The Agency does not approve clearance devices and therefore cannot implement this language on its website. However, the Agency could include a statement on the EPA website similar to:

“The Agency does not approve use of or otherwise regulate the use of clearance devices but has conducted testing on the effectiveness of some models of clearance devices in detecting required clearance levels in order to inform users.”

- 3. Proposed Terms of Label Approval Letter:** The Agency does not accept Douglas’s new proposed terms for label approval. The requirements for approving sulfuryl fluoride labels are already established as stated in the email communication and attachments sent to each registrant on July 13, 2023, requiring labels to be submitted to the Agency by **October 30, 2023**. As described in the June 2023, *Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-Entry Mitigation Measures* and on EPA’s website, [Sulfuryl Fluoride US EPA](#), data to support clearance device effectiveness can be submitted to the Agency at any time, provided it is developed according to the Agency Protocol and [Guidance on Sulfuryl Fluoride Clearance Device Testing](#). If the Agency review of the clearance device data supports the effectiveness of a clearance device, that device model will immediately be listed under Effective Devices on EPA’s website.

Please submit the revised labels with the required changes as described in the attached Final Sulfuryl Fluoride Label Table 11.7.2023. The attached label table dated 11.7.2023 corrects the editorial error of the CAP reference in the **Aeration and Re-entry** section from the previous 10.23.2023 label table. Please submit the labels via CDX using the “Registration Review” section, as described in the label letter you received on July 13, 2023. In the absence of this revised labeling, sulfuryl fluoride products will not have sufficient directions for use to adequately protect human health. Therefore, failure to submit amended labels implementing the *Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-Entry Mitigation Measures* immediately and in an adequate manner, may result in regulatory action.

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 – November 7, 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 – November 7, 2023

| Description | <i>November 7, 2023</i> Label Language for Sulfuryl Fluoride Products for Residential Fumigation | Placement on Label |
|--|---|--|
| End Use Products | | |
| <p>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.</p> | <p>“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.</p> <ol style="list-style-type: none"> 1. The applicator must post the fumigated areas with warning signs with a white background stating the following: <ol style="list-style-type: none"> 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.” | <p>In the Directions for Use under the heading “Posting of Fumigated Areas”</p> |
| <p>Site-specific Structural Fumigation Log for all end-use products containing directions 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</p> | <p>“Structural Fumigation Log requirements. The following elements for structural fumigation for each site must be documented.</p> <p>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,</p> | <p>In the Directions for Use under the heading “Site-Specific Structural Fumigation Log”</p> |

| Description | <i>November 7, 2023</i> Label Language for Sulfuryl Fluoride Products for Residential Fumigation | Placement on Label |
|---|--|--------------------|
| <p>satisfy the equivalent requirement of each element on this label.</p> <p>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.</p> | <p>state or federally required forms and/or other 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.</p> <p>1. General Information:</p> <ul style="list-style-type: none"> • Fumigation company (B) • Fumigation site address (B) • Structure type (B) • Target pest(s) (B) <p>2. Fumigant introduction:</p> <p><u>Dosing calculations:</u></p> <ul style="list-style-type: none"> • Dosage factor • Tarp condition • Under seal type • Seal condition • Wind (mph) • Volume of fumigated space (1000 cubic feet) (B) • Underseal • Temperature • Hours of Exposure <p><u>Introduction of chloropicrin and sulfuryl fluoride:</u></p> <ul style="list-style-type: none"> • Name, license number, and signature of 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 and sulfuryl fluoride. • Total ounces of warning agent chloropicrin introduced and number of introduction sites. • Cylinder serial number(s) of sulfuryl fluoride applied. • Pounds of fumigant applied. • Date and time of fumigant release. <p>3. Aeration:</p> | |

| Description | <i>November 7, 2023</i> Label Language for Sulfuryl Fluoride Products for Residential Fumigation | Placement on Label |
|---|--|---|
| | <ul style="list-style-type: none"> • Name, license number, and signature of certified applicator responsible for initiating aeration. • Name(s) of certified applicator(s) and second trained person(s) assisting with initiating aeration. • Date and time of aeration initiated. <p>4. Final clearance testing:</p> <ul style="list-style-type: none"> • Name, license number, and signature of certified applicator responsible for conducting final clearance testing. • Name(s) of certified applicators assisting final clearance testing. • Date and time final clearance testing completed. • Clearance device model type <p>5. 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.”</p> <p>6. Open Comment field: Provide an open field for additional comments or issues that is not captured in other sections of this Structural Fumigation Log.”</p> | |
| <p>Product Stewardship Plan reference for residential structural fumigations.</p> <p>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.</p> | <p>“[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.”</p> | <p>In Directions under heading “[the registrant]’s Product Stewardship Plan</p> |

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|---|---|---|
| <p>Language Regarding Portable Clearance Devices</p> | <p>Registrants, remove all references to clearance devices being “approved.” Replace language with the following statement:</p> <p>“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.”</p> | <p>In the Directions for Use under the heading “Aeration and Reentry”</p> |
| <p>Aeration and Reentry Requirements for residential structures.</p> <p>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</p> | <p>Registrants, for residential fumigations, replace the language for Aeration Procedures 1 & 2 with the revised language, which reflects the new aeration times:</p> <p>“Preparation Section</p> <p>Prepare for Aeration Procedures 1 and 2 by doing the following:</p> <ul style="list-style-type: none"> • 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. <p>Select the appropriate procedure based on the fumigation rate:</p> <p>All structures fumigated at 16 oz/MCF (1,000 cubic feet of gas) or less may be aerated using Aeration Procedures 1 or 2.</p> <p>All structures fumigated at concentrations greater than 16 oz/MCF must be aerated using Aeration Procedure 2.</p> <p>Aeration Procedure 1</p> <p>These steps must be completed in sequence.</p> <p>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</p> | <p>In the Directions for Use under the heading “Aeration and Reentry”</p> |

| Description | <i>November 7, 2023</i> Label Language for Sulfuryl Fluoride Products for Residential Fumigation | Placement on Label |
|-------------|--|--------------------|
| | <p>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.</p> <p>Step (2): 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 structures¹. During this time structures must remain posted with warning signs.</p> <p>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.</p> <p>Aeration Procedure 2 These steps must be completed in sequence.</p> <p>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.</p> <p>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 Fluoride Introduced, from the start of aeration (first opening of the seal) for residential structures.¹ During this time the structure must remain posted with warning signs.</p> <p>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.</p> | |

| Description | <i>November 7, 2023</i> Label Language for Sulfuryl Fluoride Products for Residential Fumigation | Placement on Label | | | | | | | | | | | | | | |
|--|---|--|----------------------------------|-----------------------|----|-----------------------|----|-----------------------|----|-----------------------|----|------------------------|----|------------------|----|--|
| | <p data-bbox="779 285 1335 370" style="text-align: center;">Table X. Determining Minimum Hours of Aeration Time Based on Initial Concentration of Sulfuryl fluoride Introduced</p> <table border="1" data-bbox="588 407 1528 678"> <thead> <tr> <th data-bbox="588 407 1110 475">Initial Concentration of Sulfuryl Fluoride Introduced (ounces per thousand cubic feet)</th> <th data-bbox="1110 407 1528 475">Minimum Hours of Aeration Time**</th> </tr> </thead> <tbody> <tr> <td data-bbox="588 475 1110 509">Greater than 16 to 32</td> <td data-bbox="1110 475 1528 509">14</td> </tr> <tr> <td data-bbox="588 509 1110 544">Greater than 32 to 48</td> <td data-bbox="1110 509 1528 544">16</td> </tr> <tr> <td data-bbox="588 544 1110 578">Greater than 48 to 64</td> <td data-bbox="1110 544 1528 578">18</td> </tr> <tr> <td data-bbox="588 578 1110 612">Greater than 64 to 96</td> <td data-bbox="1110 578 1528 612">20</td> </tr> <tr> <td data-bbox="588 612 1110 646">Greater than 96 to 112</td> <td data-bbox="1110 612 1528 646">22</td> </tr> <tr> <td data-bbox="588 646 1110 678">Greater than 112</td> <td data-bbox="1110 646 1528 678">24</td> </tr> </tbody> </table> <p data-bbox="617 683 1428 737">**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.</p> <p data-bbox="583 773 1520 889">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.”</p> | Initial Concentration of Sulfuryl Fluoride Introduced (ounces per thousand cubic feet) | Minimum Hours of Aeration 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 | |
| Initial Concentration of Sulfuryl Fluoride Introduced (ounces per thousand cubic feet) | Minimum Hours of Aeration 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 | | | | | | | | | | | | | | | |