

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

ProFume

Product type(s)

PT08: Wood preservatives

Authorisation number: IE/BPA 70001

R4BP asset number: IE-0000774-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	ProFume
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Douglas BLG BVBA
	Address	Avenue Marnix 23, 5th floor 1000 Brussels Brussels Belgium
Authorisation number	IE/BPA 70001	
<i>R4BP asset number</i>	IE-0000774-0000	
Date of the authorisation	25/01/2010	
Expiry date of the authorisation	31/12/2024	

1.3. Manufacturer(s) of the product

Name of manufacturer	Douglas Products
Address of manufacturer	1550 E. Old Highway 64068 Liberty, Missouri United States (the)
Location of manufacturing sites	901 Loveridge Road 94565 Pittsburgh California United States (the)

1.4. Manufacturer(s) of the active substance(s)

Active substance	sulfuryl fluoride
Name of manufacturer	Douglas Products
Address of manufacturer	1550 E. Old Highway 64068 Liberty, Missouri United States (the)
Location of manufacturing sites	901 Loveridge Road 94565 Pittsburgh California United States (the)

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
sulfuryl fluoride	sulfuryl difluoride	active substance	2699-79-8	220-281-5	99,8

2.2. Type(s) of formulation

GA Gas

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>H280: Contains gas under pressure; may explode if heated.</p> <p>H330: Fatal if inhaled.</p> <p>H370: Causes damage to organs Kidney if inhaled.</p> <p>H373: May cause damage to organs Nervous system, respiratory system, kidney through prolonged or repeated exposure if inhaled.</p> <p>H400: Very toxic to aquatic life.</p> <p>EUH210: Safety data sheet available on request.</p> <p>EUH401: To avoid risks to human health and the environment, comply with the instructions for use.</p>
Precautionary statements	<p>P260: Do not breathe gas.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P284: [In case of inadequate ventilation] wear respiratory protection.</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P310: Immediately call a POISON CENTER.</p> <p>P308: IF exposed or concerned:</p> <p>P314: Get medical advice if you feel unwell.</p> <p>P405: Store locked up.</p> <p>P410+P403: Protect from sunlight. Store in a well-ventilated place.</p>

4. AUTHORISED USE(S)

4.1. Use description

Table 1. A gas fumigant for the disinfestation of wood from wood destroying pests. Uses include structures/rooms (e.g churches, houses), wooden objects and timber in fumigation chambers, shipment containers and in stacks in tarpaulins.

Product type	PT08: Wood preservatives
Where relevant, an exact description of the authorised use	A gas fumigant for the disinfestation of wood from wood destroying pests. Uses include structures/rooms (e.g churches, houses), wooden objects and timber in fumigation chambers, shipment containers and in stacks in tarpaulins. For trained/specialised/licensed professional use only. ProFume may not be used for treatment of food or feed items.
Target organism(s) (including development stage)	Scientific name: <i>Anobium punctatum</i> De Geer Common name: Wood infesting beetles Development stage: all life stages: eggs, larvae, juveniles, adults Scientific name: <i>Lyctus brunneus</i> Common name: wood infesting beetles Development stage: all life stages: eggs, pupae, larvae, nymphs and adults Scientific name: <i>Hylotrupes bajulus</i> L. Common name: wood infesting beetles Development stage: all life stages: eggs, pupae, larvae, nymphs and adults Scientific name: <i>Bursaphelenchus xylophilus</i> Common name: Pinewood nematode Development stage: all life stages: eggs, pupae, larvae, nymphs and adults
Field(s) of use	indoor use
Application method(s)	Method: fumigation Detailed description: Prior to undertaking fumigation, with ProFume it is essential that the enclosure (structure, building, chamber, vessels, etc) that is to be fumigated is made as air tight as possible to minimise gas losses. Before the fumigant is introduced the area must be inspected to confirm that it is vacated and that all required fumigation preparations have been completed. All entries to the area must be immediately closed and locked after inspection. The fumigant gas is then introduced by a fumigator (operator) from the outside of the enclosure via introduction tubes leading from the cylinders to purposely positioned outlet site(s) within the enclosure. After completed fumigation the final step is aeration of the enclosure. Re-entry to the fumigation area occurs after the aeration phase. The exposure concentration of sulfuryl fluoride in the air must not on any occasion exceed 3 ppm which has been established as the limit value for exposure of operators and

	<p>the AOEC for bystanders. Fumigators/operators must wear or have constant, immediate access to respiratory protective equipment (SCBA) during the whole fumigation process in order not to be exposed to levels above 3 ppm. Further monitoring of the concentration of sulfuryl fluoride outside the fumigated enclosure, by the compulsory use of monitoring equipment, is a prerequisite to ensure safe level of exposure for both operator and bystanders. ProFume may only be used by professional operators with documented education to ensure that risk mitigation measures are taken. There is no mixing and loading, ProFume is delivered as a ready-to-use product in a cylinder as pressurized liquid. At the end of the treatment, the operator aerates remotely or, if required, enters the treated area wearing positive-pressure, self contained breathing apparatus to initiate aeration. At the end of the aeration period, the operator checks that the air concentration is below 3 ppm and then declares the area clear for re-entry. The dosage is defined as the product of fumigant concentration X exposure time (CTP) which is measured as g h/m³. The maximum target concentration is 128 g/m³. The Fumiguide program (supplied by Dow AgroSciences) must be used to calculate the required dosage and the amount of ProFume needed. The dosage will be specific for each fumigation.</p> <p>The following parameters which are taken into account in the Fumiguide affect the amount of fumigant required and the dosage: volume area to be fumigated, pest species, pest life stage, temperature and exposure time..</p>
Application rate(s) and frequency	<p>Application rate: See below - The maximum concentration is 128 g/m³</p> <p>Dilution (%): 100</p> <p>Number and timing of application: The dosage required for effective control is derived from the product (P) of fumigant concentration (C) x time (T), referred to as the CTP. The CTP is given in g-h/m³ (gram hours per cubic metre). The proposed product (ProFume) label does not provide target dosages because computer programmes; ProFume Fumiguide calculator(s) are required for this purpose. The dosage will be specific for each fumigation incorporating the biological factors (e.g. pest species and pest life stage) and the gas retention rate to determine the initial target concentration. The volume of the fumigated site is then factored in to determine the amount (weight) of the fumigant required for the specific target pest, site, exposure period and environmental conditions. Monitoring of the fumigant concentration is undertaken during the fumigation and if needed further amounts are added or changes are made concerning the exposure period to ensure that the correct dosage is applied. The maximum concentration is 128 g/m³.</p>
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Bottle, Metal: , 56.7Kg</p> <p>ProFume is contained as a liquefied gas under pressure in steel cylinders with a net weight of 56.7 Kg. The volume of the cylinder is approximately 75 litres.</p>

	See above. Plus: For trained/specialised professional use only
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4.1.1. Use-specific instructions

For trained/specialised professional use only

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

No measures specific to use

4.1.4. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No measures specific to use

4.1.5. Where specific to the use, the instructions for safe disposal of the product and its packaging

No instructions specific to use

4.1.6. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

No conditions of storage specific to use

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Prior to undertaking fumigation, with ProFume it is essential that the enclosure (structure, building, chamber, vessels, etc) that is to be fumigated is made as air tight as possible to minimise gas losses.

Before the fumigant is introduced the area must be inspected to confirm that it is vacated and that all required fumigation preparations have been completed.

All entries to the area must be immediately closed and locked after inspection.

The fumigant gas is then introduced by a fumigator (operator) from the outside of the enclosure via introduction tubes leading from the cylinders to purposely positioned outlet site(s) within the enclosure.

After completed fumigation the final step is aeration of the enclosure. Re-entry to the fumigation area occurs after the aeration phase.

The exposure concentration of sulfuryl fluoride in the air must not on any occasion exceed 3 ppm which has been established as the limit value for exposure of operators and the AOEC for bystanders.

Fumigators/operators must wear or have constant, immediate access to respiratory protective equipment (SCBA) during the whole fumigation process in order not to be exposed to levels above 3 ppm.

Further monitoring of the concentration of sulfuryl fluoride outside the fumigated enclosure, by the compulsory use of monitoring equipment, is a prerequisite to ensure safe level of exposure for both operator and bystanders.

ProFume may only be used by professional operators with documented education to ensure that risk mitigation measures are taken.

There is no mixing and loading, ProFume is delivered as a ready-to-use product in a cylinder as pressurized liquid.

At the end of the treatment, the operator aerates remotely or, if required, enters the treated area wearing positive-pressure, self contained breathing apparatus to initiate aeration.

At the end of the aeration period, the operator checks that the air concentration is below 3 ppm and then declares the area clear for re-entry.

The dosage is defined as the product of fumigant concentration X exposure time (CTP) which is measured as g h/m³.

The maximum target concentration is 128 g/m³.

The Fumiguide program (supplied by Douglas Products) must be used to calculate the required dosage and the amount of ProFume needed.

The dosage will be specific for each fumigation. The following parameters which are taken into account in the Fumiguide affect the amount of fumigant required and the dosage: volume area to be fumigated, pest species, pest life stage, temperature and exposure time.

5.2. Risk mitigation measures

Appropriate Engineering Controls:

Engineering controls: Use engineering controls to maintain airborne level below exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, use only in enclosed systems or with local exhaust ventilation. Exhaust systems should be designed to move the air away from the source of vapor/aerosol generation and people working at this point. Lethal concentrations may exist in areas with poor ventilation.

Individual protection measures:

Eye/face protection: For handling the gas, wear safety glasses (with side shields). When contact with the liquid (condensed gas) is possible, wear chemical goggles. Safety glasses (with side shields) should be consistent with EN 166 or equivalent. Chemical goggles should be consistent with EN 166 or equivalent.

Skin protection.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

Hand protection: Chemical protective gloves should not be needed when handling this material. Consistent with general hygienic practice for any material, skin contact should be minimized.

Other protection: Wear clean, body-covering clothing.

Respiratory protection: Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. When respiratory protection is required, use an approved positive-pressure self-contained breathing apparatus or positive-pressure airline with auxiliary self-contained air supply. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. In confined or poorly ventilated areas, use an approved self-contained breathing apparatus or positive pressure air line with auxiliary self-contained air supply.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First Aid Measures:

General advice: First aid responders should pay attention to self-protection and use the recommended protective clothing (chemical resistant gloves, splash protection).

Inhalation: Move person to fresh air. If person is not breathing, call an emergency responder or ambulance, then give artificial respiration; if mouth-to-mouth use rescuer protection (pocket mask etc.). Call a poison control centre or doctor for treatment advice. If breathing is difficult, oxygen should be administered by qualified personnel. If the person is not breathing and has no pulse, consider cardiopulmonary resuscitation (CPR); use pocket resuscitation mask, bag valve mask etc., to avoid risk of exposing the rescuer.

Skin contact: Take off contaminated clothing. Rinse immediately with plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice. In case of frostbite, immediately flush skin with plenty of water for 15 minutes. Seek medical attention. Suitable emergency safety shower facilities should be available.

Eye Contact: In case of frost bite; immediately flush eyes with water, remove contact lenses, if present, after the first 5 minutes, then continue flushing eyes for at least 15 minutes. Obtain medical attention promptly, preferably from an ophthalmologist. Suitable emergency eye wash facilities should be immediately available.

Ingestion: Call a poison centre or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control centre or doctor. Never give anything to mouth to an unconscious person.

Most Important symptoms and effects, both acute and delayed: It is predicted that persons exposed to sulfuryl fluoride will show little evidence of intoxication at first, unless the concentration is very high (greater than 400 ppm). Early symptoms of exposure to sulfuryl fluoride are respiratory irritation and central nervous system depression. Excitation may follow and slow or garbled speech may be noted. May cause asthma-like (reactive airways) symptoms.

Exposure to the substance may cause frostbite to eyes and skin.

Indication of any immediate medical attention and special treatment needed:

Notes to physician: Maintain adequate ventilation and oxygenation of the patient. Sulfuryl fluoride is a gas which has no warning properties such as odor or eye irritation. The prediction of possible human effects is based in part on observations made on laboratory animals. Treat for frostbite if present (eyes, skin) with gentle rewarming by water irrigation for at least 15 minutes. It is predicted that persons exposed to sulfuryl fluoride will show little evidence of intoxication at first, unless the concentration is very high (greater than 400 ppm). Early symptoms of exposure to sulfuryl fluoride are respiratory irritation and central nervous system depression. Excitation may follow. Slowed movement, reduced awareness, and slow or garbled speech may be noted. It is essential to keep such an individual at bed rest for at least 24 hours. Clinical observations should be directed at the pulmonary, hepatic, and renal systems. Prolonged exposure can produce lung irritation, pulmonary edema, nausea, and abdominal pain. Repeated exposure to high concentrations can result in significant lung and kidney damage. Convulsions may ensue with respiratory arrest being the terminal event. Assisted respiration may be necessary. Clinical observation is essential. There is no known antidote for overexposure to sulfuryl fluoride. May cause asthma-like (reactive airways) symptoms. Bronchodilators, expectorants, antitussives and

corticosteroids may be of help. Respiratory symptoms, including pulmonary edema, may be delayed. Persons receiving significant exposure should be observed 24-48 hours for signs of respiratory distress. Consider administering a complete aerosol corticosteroid metered dose inhaler (100-150 shots) or equivalent as initial preventive treatment for incipient pulmonary edema. Consider administering 250-1000 mg prednisolone IV on the first day of treatment. Treat for frostbite, if present. No specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient. Have the Safety Data Sheet, and if available, the label with you when calling a poison control center or doctor, or going for treatment. Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

5.4. Instructions for safe disposal of the product and its packaging

When the cylinder is empty, close the valve, screw safety nut into valve outlet and replace protection cap before returning to supplier. Only Douglas Products is authorised to refill cylinders. Do not use cylinder for any other purpose. Follow Douglas Products instructions for return of empty or partially empty cylinders. Promptly return all empty cylinders and/or unused fumigant to the supplier of ProFume. If there is a need for safe disposal of ProFume it can be hydrolysed with alkaline solutions.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Cylinders containing ProFume should be stored away from heat and ignition sources in a well-ventilated location away from work areas and offices.

All cylinders (full, partially full or empty) should be stored in a secured area in an upright (vertical) position with caps securely in place.

Cylinders should be secured in a position so they cannot be knocked over.

Cylinders should not be subject to rough handling.

The cylinder must not be re-used for any other purpose.

The empty cylinder must be returned as instructed by the supplier.

A shelf-life of 24 months has been supported.

6. OTHER INFORMATION