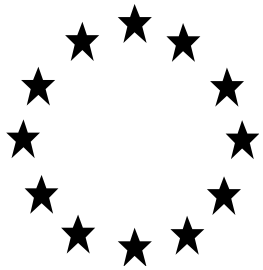
Directive 98/8/EC concerning the placing of biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Draft Assessment Report



SULFURYL FLUORIDE
Product-type 18
(Insecticide)

20 February 2009

Annex I – SWEDEN

Sulfuryl fluoride (PT 18)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 20 February 2009 in view of its inclusion in Annex I to Directive 98/8/EC

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of sulfuryl fluoride as product-type 18 (insecticide), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I to the Directive.

Sulfuryl fluoride (CAS no. 2699-79-8) was notified as an existing active substance, by Dow AgroSciences GmbH, hereafter referred to as the applicant, in product-types 8 (wood preservative) and 18 (insecticide).

Commission Regulation (EC) No 1451/2007 of 4 November 2003[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, Sweden was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for sulfuryl fluoride as an active substance in Product Type 18 was 30 April 2006, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 11 April 2006 Swedish competent authority received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 22 June 2006.

On 19 June 2007, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 19 June 2007. The competent authority report included a recommendation for the inclusion of sulfuryl fluoride in Annex I to the Directive for product-type 18.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 27 September 2007. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

[1] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

[2] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

On the basis of the final competent authority report, the Commission proposed the inclusion of sulfuryl fluoride in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 20 February 2009.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 20 February 2009.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include sulfuryl fluoride in Annex I to Directive 98/8/EC for product-type 18. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 18 that contain sulfuryl fluoride. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing sulfuryl fluoride for the product-type 18, which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to:

i. compliance with the particular requirements in the following sections of this assessment report,

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

[3] http://ec.europa.eu/comm/environment/biocides/index htm

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Summary information on the identity of sulfuryl fluoride can be found in Appendix I and the 'Confidential Annex' of the competent authority report.

Sulfuryl fluoride is a colourless gas with a boiling point of -54 °C and a melting point of -137 °C. Its vapour pressure was calculated to be 1.6 MPa at 20 °C and the vapour density relative to air is 3.5. Its solubility in water was determined to be 1.04 g/L in unbuffered water (pH=2.5) at 20 °C and it is readily soluble (>50 g/L) in acetone and ethyl acetate and moderately soluble in various other tested organic solvents. Its log P_{ow} was measured to be 0.14 at 20 °C in unbuffered water and since the molecule does not dissociate (theoretical consideration) no pH effect is anticipated. However, as sulfuryl fluoride rapidly hydrolyses under alkaline conditions a significantly lower log P_{ow} can be expected for the alkaline range. A 90% saturated solution of sulfuryl fluoride in water has a surface tension of 67.5 mN/m. It is non-flammable, non-explosive and has no oxidizing properties.

The representative biocidal product named ProFume solely consists of technical sulfuryl fluoride (typical purity 99.8%) and the above described properties does therefore also apply to the product. ProFume is stored in steel cylinders as a liquefied gas under pressure.

The methods of analysis for sulfuryl fluoride as manufactured, and for the determination of impurities, have been validated. The method of analysis in air, which is appropriate for the area of use assessed, has been validated. Brief summaries of the analytical methods used can be found in Appendix I (Chapter 2).

2.1.2. Intended Uses and Efficacy

Sulfuryl fluoride is used as fumigant for professional use only to control stored products insects in emptied food processing facilities. Comprehensive fumigation studies have confirmed that sulfuryl fluoride is an effective fumigant for the control of stored product insects.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Sulfuryl fluoride is currently classified according to the Commission Directive 2004/73/EC (adapting to technical progress for the twenty-ninth time Council Directive 67/548/EEC) which updates Annex I to Directive 67/548/EEC.

Since the active substance and the biocidal product are identical they have the same classification and labelling requirements.

Hazard symbol:	T	Toxic
(for labelling)	N	Dangerous for the environment
Indication of danger:	Skull and Crossbones	
	Dead Fish and Tree	
Risk Phrases:	R23	Toxic by inhalation
(for labelling)	R48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation
	R50	Very toxic to aquatic organisms
Safety Phrases: (for labelling)	S1/2	Keep locked up and out of reach of children.
	S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
	[S60[4]	This material and its container must be disposed of as hazardous waste.]
	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets.
	S63	In case of accident by inhalation: remove casualty to fresh air and keep at rest.

[4] S60: RMS agrees with the applicant that this safety phrase is not suitable for sulfuryl fluoride since the cylinders containing sulfuryl fluoride are recycled and may be used for many years.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification and effects assessment

The biocidal product (ProFume) and the active substance are one and the same, with a typical purity of 99.8% (w/w). A database on the toxicity of sulfuryl fluoride was submitted by the applicant. It included studies on toxicokinetics, acute toxicity, short-term (subacute and subchronic) toxicity, genotoxicity, reproductive and developmental toxicity, chronic toxicity, carcinogenicity and neurotoxicity.

^{35}S-sulfuryl fluoride is rapidly absorbed via inhalation exposure, achieving maximum concentrations of radioactivity in plasma and red blood cells (RBC) at the end of the 4-hours exposure period. The ^{35}S is rapidly excreted, primarily via the urine, even during the exposure period. Plasma and RBC initial half-lives are 1-2.5 hours and the terminal half-life of radioactivity is ~2.5-fold longer in RBC than plasma. The identification of fluorosulphate and sulphate in blood and urine suggests that sulfuryl fluoride is first hydrolysed to fluorosulphate, with release of fluoride, followed by further hydrolysis to sulphate and release of the remaining fluoride. This is supported by increases in fluoride in blood and urine. Seven days post-exposure, small amounts of radiolabel are evenly distributed among tissues suggesting ^{35}S incorporation into amino acids, but the exact chemical composition was not determined. Radioactivity is recovered mainly in tissues at the site of first exposure to the gas. The data suggest that systemic toxicity elicited by sulfuryl fluoride may be due to the release of fluoride ions, rather than a direct toxic action of sulfuryl fluoride per se. There is no information on the distribution of fluoride in the bones and the teeth in the study submitted. However, this distribution is well documented in the open literature (one recent review by IPCS can be found in Environmental Health Criteria 227, 2002). It has been discussed to use dental fluorosis as a marker for skeletal fluorosis when information about fluoride in the bones is missing. However, the bone effects of fluoride are considered to be at least threefold less sensitive than dental fluorosis on the basis of human observations. The additional fluoride intake of workers by exposure to sulfuryl fluoride is calculated to be 0.02 mg/kg bw/day. EFSA has set an upper limit for fluoride intake at 0.12 mg/kg bw/day. This limit is however for adult lifetime daily exposure, while exposure to sulfuryl fluoride is more limited in duration.

Sulfuryl fluoride is neither toxic nor irritative via exposure to skin. As a gas, the acute toxicity via inhalation has been extensively investigated. Several studies in rats and one of two studies in mice reported 4-hour LC_{50} values above 2 mg/l. The one exception is a study in mice with a 4 hour LC_{50} value between 1.668 and 2.802 mg/l. Since sulfuryl fluoride is a gas, no eye irritation test or skin sensitisation study has been conducted. These toxic properties of sulfuryl fluoride have not been suggested by the experience in humans over a period of 40 years of use of Vikane (99.8% w/w sulfuryl fluoride, a product identical to ProFume).

Sulfuryl fluoride has been studied for short-term inhalation toxicity in rats, dogs, mice and rabbits. In 14-day studies the lowest NOAEL was 30 ppm in mice. This was also the NOAEL in 90-day studies in mice and rabbits. In these studies the LOAEL was 100 ppm based on vacuolation in the brain. The severity was slightly greater in the affected rabbits at 100 ppm but the frequency was much higher in mice at this level. The severity of brain lesions increased with exposure concentration and included necrosis and vacuolation in the cerebrum of rabbits, respiratory inflammation and tetany/tremors in dogs, and mild renal changes in rats. In a 1-year study in dogs the NOAEL was 20 ppm based on slight alveolar changes at 80 ppm. A higher

concentration of 200 ppm was not tolerated beyond 9 months. Microscopic dental fluorosis was evident in some studies. It can be debated whether dental fluorosis is an adverse effect or only a cosmetic problem. The scientific panel of EFSA has come to the conclusion that moderate dental fluorosis, characterised by staining and minute pitting of the teeth, is adverse but not milder forms with white spots and opaque striation. For sulfuryl fluoride, as a biocide in product type 8, the Technical Meeting (TMIII05) agreed that it should be considered adverse but not relevant due to exposure patterns. This argument is also relevant for sulfuryl fluoride as a biocide in product type 18 since the exposure pattern is the same.

The overall evaluation of the genotoxic property of sulfuryl fluoride is based on several related studies on the substance. The results of genotoxicity tests of sulfuryl fluoride are negative in bacterial cell mutation tests, in *in vitro* UDS test with mammalian cells and in *in vivo* micronucleus test with bone marrow tissue. Two *in vitro* tests for mutagenicity and clastogenicity in mammalian cells were positive. These results show that sulfuryl fluoride is genotoxic *in vitro*. However, this *in vitro* genotoxic property is not supported by an *in vivo* micronucleus test or an *in vitro* UDS test. Together with the negative results of carcinogenicity test in two carcinogenicity studies, it shows that sulfuryl fluoride does not act as a genotoxic or mutagenic substance *in vivo*. The mechanisms underlying the positive results of two *in vitro* tests (clastogenicity and mutagenicity) are likely the formation of fluoride ions in the test system. Sulfuryl fluoride is known to release fluoride ions, which are known from previous studies to induce mutations and chromosomal damage in mammalian cells *in vitro*. In the *in vitro* systems there is no elimination of the fluoride ions and the concentration is probably higher than it would be *in vivo* after exposure to sulfuryl fluoride. Data is not conclusive regarding the genotoxicity property of fluoride *in vivo.* The evidences are generally weak to support that fluoride is genotoxic *in vivo*. Overall, sulfuryl fluoride is not considered to be genotoxic *in vivo*.

In rats and mice the NOAEL was 20 ppm. This was based on chronic progressive glomerular nephrosis and respiratory tract irritation in male and female rats and slight histopathological changes in the brain and thyroid glands of male and female mice, at 80 ppm. Sulfuryl fluoride is not tumourigenic or carcinogenic in male or female rats or mice at tested concentrations up to and including 80 ppm.

Sulfuryl fluoride had no effect on reproductive parameters when inhaled by rats in a 2-generation reproduction study at concentrations up to and including 150 ppm for 6 hours/day, 5 - 7 days a week for up to 20 consecutive weeks. The parental NOAEL was 5 ppm based on an increased incidence of aggregates of alveolar macrophages in adult F0 and F1 males and females at 20 ppm. The NOAEL in offspring was 20 ppm based on reduced growth during lactation at 150 ppm. Sulfuryl fluoride is not teratogenic in either rats or rabbits. In the rat, there were no adverse effects on dams or offspring at concentrations up to and including 225 ppm. In rabbits the developmental NOAEL was 75 ppm based on reduced body weights of dams and offspring at 225 ppm.

Neurotoxicity of sulfuryl fluoride has been investigated in studies with three different exposure periods: acute (2-day), subchronic (13-week) and chronic (1-year). The most sensitive effect on the nervous system was a change in evoked potentials (visual, auditory and somatosensory) as shown in a 13-week subchronic study. In general these evoked potentials became slower at 100 ppm. At 300 ppm were histological effects evident as mild vacuolation in the brain. The NOAEL in this study was 30 ppm.

In an acute neurotoxicity study, these evoked potentials as seen in the13-week study did not change at the top dose level of 300 ppm. NOAEL for this acute neurotoxicity study is 300 ppm. This result, together with those from mechanistic and subchronic studies showed that the slowing of evoked potentials by sulfuryl fluoride is time-dependent.

Observations from a 1-year chronic neurotoxicity study included a FOB, motor activity tests, fore- and hindlimb grip strength, hindlimb landing foot splay and neurohistopathology with perfusion fixation. There were no effects on the nervous system at the top dose tested (80 ppm). The NOAEL for neurotoxicity was 80 ppm. At the same dose level in this study, there were several changes caused by chronic toxicity of sulfuryl fluoride. This indicates that these parameters of neurotoxicity used in this study are less sensitive than those general toxicity end points. Dental fluorosis occurred in males at 20 ppm. The NOAEL for general effects was 20 ppm based on renal changes and increases in aggregates of alveolar macrophages. The neurotoxic effects in the inhalation toxicity studies were the basis for classification as R48/20.

Acute exposure to sulfuryl fluoride can be lethal. Poisoning symptoms are unspecific, including eye and respiratory irritation, sore throat and cough. Some of these observations, i.e. eye irritation, may be caused by the use of chloropicrin together with Vikane/ProFume. Other complaints include flu-like symptoms of nausea, diarrhoea, fever and headache, shortness of breath or respiratory distress. According to PROSAR (a human health poison control centre) records about 3% of the cases need medical care or treatment. 87% of the cases in PROSAR records (1997 to 2002) were either asymptomatic or had only minor symptoms. Manufacturing plant health surveillance examinations revealed no significant sulfuryl fluoride-related health problems among employees.

Settings of ADI and ARfD is not applicable since there will be no exposure of sulfuryl fluoride to food or drinking water when used as a fumigant to control stored product insects (SPIs).

Because sulfuryl fluoride is a gas fumigant, it is considered the term AOEC as an air concentration (ppm) should be used instead of AOEL as an internal dose (mg/kg bw/day). This is achieved by using the different breathing rates of rats, mice and humans in the calculations.

The proposed use of ProFume is as fumigant to control stored product insect pests. The treatments are intended for fumigation of emptied food processing facilities. Fumigation of structures is considered to be worst-case in terms of amount of sulfuryl fluoride used and greater difficulties to seal compared to other fumigation scenarios (e.g. container fumigation). Individual structures (like houses and churches) are fumigated infrequently, i.e. once over periods of many years, while food processing facilities are fumigated generally once a year just like mills. Thus, the potential exposure of operator (fumigators), bystanders (general population) and re-entry-workers (workers in the food processing facilities) is acute, although operators may be exposed to repeated acute exposures.

Exposure to sulfuryl fluoride is in most cases limited to two working days in any week for structural fumigations and the AOEC could be based on a specific acute study conducted on sulfuryl fluoride, and a 100 fold safety factor. In this case, a fumigator could be exposed to a constant air concentration of 6 ppm for 8 hours a day on two consecutive days. However, this approach does not take repeated exposure into consideration. Even if each mill fumigation only last two days the fumigators may repeat this short exposure for several weeks. There is a concern about the possible accumulation of neurotoxic effects after repeated exposure and it is not known how long a rest period between exposures is needed to prevent cumulative effects. To cover these aspects a subchronic study in mice was used for the calculation of the AOEC

for operators. This would represent the AEC_{medium}. The calculation resulted in an AOEC of 1 ppm, which is the air concentration that an operator could be exposed to for a full working day over a longer period of time.

For bystanders the exposure is considered acute and the acute rat neurotoxicity study was used as a starting point for the AOEC. This would represent the AEC_{acute}. Bystanders, in a residential situation, theoretically may be exposed for periods longer than a working day. Based on a combination of body weight and inhalation rate, the most sensitive subgroup of the bystander population was shown to be infants, for which the proposed AOEC is 3 ppm. This is a 24-hour TWA value.

Even though the AOEC for operators was calculated to be 1 ppm it is suggested to set a limit value of 3 ppm, when operators must leave the area and put on self-contained breathing apparatus (SCBA). The use pattern is more similar to the acute study used for bystanders, which for operators would lead to an AOEC of 6 ppm. Since this approach does not take repeated acute exposures into consideration the "true" value is probably somewhere between 1 and 6 ppm. A limit value of 3 ppm would be harmonised with the evaluation for PT 8. It would also be an advantage not to have different values for operators and bystanders.

The $AEC_{chronic}$ was not considered necessary for this risk assessment due to the exposure pattern, but it was calculated anyway. The 18 month study in mice was used for the calculation that resulted in an $AEC_{chronic}$ of 0.4 ppm.

For local respiratory tract irritation, an AOEC of 3 ppm would provide a minimum margin of safety of 33 against the most sensitive of four species investigated over a 2-week (10-day) exposure period. Over a 13-week (65-day) exposure period in dogs and rats the margin is 67 and 100, respectively. For this end point, these margins of safety could be considered acceptable and do not alter the proposal for an AOEC of 3 ppm for bystanders, especially as the exposure for bystanders is considered to be acute. For operators the AOEC of 1 ppm is based on a subchronic study where the respiratory tract was examined and no effects were seen.

2.2.1.2. Exposure assessment and risk characterisation

Exposure of operators, i.e. fumigator and aerator, to sulfuryl fluoride, has been studied in 10 mill fumigation trials (mill fumigation is one intended use when sulfuryl fluoride is currently being evaluated under Directive 91/414/EEC). When sulfuryl fluoride is evaluated as PT18 (fumigation of emptied food processing facilities), mill fumigation is considered to represent any structural fumigation scenario. In these studies the potential exposures associated with various tasks were evaluated by sampling air from the breathing zone of the operators during the tasks. The results show an average potential exposure below 1 ppm (TWA). For European mills the mean 8 hour TWA was 0.40 ppm, and for European and US mills combined it was 0.92 ppm. Since these values are averages it is true that the concentration occasionally will be higher than 1 ppm for shorter periods. However, for shorter periods (2 days) the AOEC for operators would be 6 ppm based on the acute neurotoxicity study. These concentrations are however potential exposures, without reduction for SCBA. Thus, it is very important that appropriate measures are taken to ensure that operators are not exposed to sulfuryl fluoride levels above 3 ppm. In view of the inhalation toxicity property of sulfuryl fluoride and the potentially repetitive exposure risk of operators, it is essential for fumigators to immediately leave the area and put on SCBA in a safe zone whenever the atmospheric concentration of

sulfuryl fluoride reaches 3 ppm. To have the best protection, operators should wear SCBA when using sulfuryl fluoride fumigant.

Table 2.2.1.2-1 Summary of the potential sulfuryl fluoride exposure to operators: A comparison to the AOEC value of 1 ppm and the limit value of 3 ppm

Exposure scenario		Potential exposure (mean 8-hour TWA air concentration) [b]				
		ppm	mg/kg [c]	% AOEC	% limit value	MOE [d]
Introduction of gas [a]		0	0	-	-	-
Fumigation	min.	0.04	0.002	4.0	1.3	1950
	max.	3.35	0.20	335	112	20
	mean	1.1	0.06	110	37	65
Aeration	min.	0.19	0.01	19	6.3	390
	max.	1.48	0.09	148	49	43
	mean	0.64	0.04	64	21	97
Overall	mean	0.92	0.05	92	31	78

[a] SCBA (self-contained breathing apparatus) must be worn during introduction of gas.
[b] Values from structural fumigation trials as presented in III-B6.6/02, operator exposure.
[c] Male adult, body weight 70 kg, inhalation rate 10 m^3/working_day (Exposure factors handbook, EPA, 1997).
[d] NOAEL for NOAEC setting is 30 ppm, which equals to 3.9 mg/kg bw in mice (MOE=margin of exposure).

Bystander exposure can be incidental or residential. Incidental bystander exposure comprises people who may pass by during fumigation or aeration and receive a very transient exposure lasting a few seconds or minutes at the most. The worst-case for bystanders is the residential situation. Residential bystander exposure comprises people who are living/staying near the structure to be fumigated for up to 24 h/day and for days and who could potentially be exposed for longer time, but still acute, since the structures are only fumigated at very irregular intervals. The potential exposure resulting from the use of sulfuryl fluoride as a fumigant for any bystander has been measured in 11 individual structural (i.e. mill) fumigation trials.

According to these studies, there is no risk for bystanders to be exposed to sulfuryl fluoride concentrations above AOEC at a distance >10 metres from the mill. Infants are identified as the most sensitive group for the exposure in this case. For this group MOE is 94 for the highest measured level of sulfuryl fluoride at a nominal distance of 10 metres from the mill (in reality 9.1 m). Therefore, a 10-metre exclusion zone could be proposed for bystanders. Should, however, the monitored levels of sulfuryl fluoride at distances less than 10 metres from any structure being fumigated indicate that the exclusion zone needs to be expanded outwards this must of course be done. In conclusion, appropriate measures to protect bystanders during fumigation and venting of treated buildings or other enclosures must be taken. The exposure level of sulfuryl fluoride in air shall not exceed 3 ppm which has been established as the AOEC for bystanders.

Table 2.2.1.2-2 Summary of the potential sulfuryl fluoride exposure to bystanders: A comparison to the AOEC value of 3 ppm

Inhalation			Bystander inhalational exposure (mg/kg bw) [b]								
Nominal distance	Exposure [a] (ppm)		Adult			6 to 8-year old			up to 2-year old		
			level	% AOEC	MOE [c]	level	% AOEC	MOE [c]	level	% AOEC	MOE [c]
10 m	min.	0.19	0.02	6	3400	0.031	6	2194	0.044	6	1545
	max.	(4.47) [d] 3.09 [e]	(0.47) 0.37	(151) 103	(145) 184	(0.739) 0.512	(150) 103	(92) 130	(1.038) 0.718	(150) 103	(66) 94
25 m	min.	0.15	0.02	5	3400	0.025	5	2720	0.035	5	1942
	max.	1.56	0.16	53	425	0.258	52	263	0.362	52	187

[a] Unidirectional 24-hour TWA air concentration from 11 fumigation trials (III-B6.6/02, bystander exposure).

[b] Absorption factor is 10%. Body weight is 60 kg for adults (agreed at TMIII05), 25.4 kg for 6 to 8 years old children and 12.3 kg for 2 years old children (Exposure factors handbook, EPA, 1977). Inhalation rate is 15.2 m^3/day for adult males; 17 m^3/day for 15 years old males; 10 m^3/day for 6 to 8 years old children and 6.8 m^3/day for 2 years old children (Exposure factors handbook, EPA, 1977).

[c] NOEL 300 ppm = 68 mg/kg body weight.

[d] This value is from a mill fumigation trial where an accidental leakage occurred from a connected unsealed office area which was unintentionally fumigated III-B6.6/02G2, K27). The distance from the point source (i.e. the office) was shorter than that recorded as nominal, therefore this value was measured about 3.7 m from the treated structure. The 10 m value from the unsealed fumigated office was estimated to be 2.86 ppm.

[e] This value is from a regular fumigation monitoring (III-B6.6/02G2, K27). This value was actually measured 9.1 m from the mill.

Re-entry refers to people who re-enter the fumigated structure. The AOEC for re-entry (i.e., the re-entry level) is also 3 ppm.

2.2.2. Environmental Risk Assessment

Sulfuryl fluoride is a gas and will remain as a gas under normal environmental conditions. Sulfuryl fluoride is released to the environment after treatment when the sealed structure is vented. Release of sulfuryl fluoride can also be expected during fumigation due to leakage from sealed enclosures. It can be expected that sulfuryl fluoride either leaked from a treated enclosure or vented to the atmosphere will remain primarily in the air phase due to its physical properties, i.e. the very high vapour pressure and Henry's law constant (0.16 MPa m^3 mol^{-1}) and the relatively moderate water solubility (1.04 g/l). This has also been supported by the fugacity modelling performed which showed that >99.99% of emissions of sulfuryl fluoride will at equilibrium partition to the atmosphere. The environmental compartment of greatest concern for sulfuryl fluoride is therefore considered to be the atmosphere.

2.2.2.1. Fate and behaviour in air

Attempts have been made to measure the concentration of sulfuryl fluoride in background tropospheric air. At the time of submission of the dossier for PT 8 as well as for PT18, there were no data available where sulfuryl fluoride had been positively identified in any samples of remote tropospheric air. Therefore the predicted environmental concentration of sulfuryl fluoride in the troposphere ($PEC_{air\text{-}global}$) was assumed to be 2.1 ng/m^3 (= 0.5 ppt) which was equivalent to the limit of detection determined for analyses of remote tropospheric air samples. This value is in relative agreement with the $PEC_{air\text{-}global}$ predicted with fugacity modelling which was 0.37 ng/m^3, equivalent to 0.088 ppt, using annual emission estimates for 1992-2000

as input value to the model. It is also in agreement with the more recent modelling using the emission estimate for 2005 as input value. From this modelling the $PEC_{air\text{-}global}$ was predicted to be 0.848 ng/m^3, (= 0.2 ppt).

In December 2006 new data on measurements of sulfuryl fluoride levels in atmospheric air were presented on a poster at the American Geophysical Union meeting in San Francisco, US. This new data have not yet been published in the peer-reviewed literature and must therefore be considered to be preliminary. In any case, the new data indicated that the sulfuryl fluoride concentrations in air in the northern hemisphere was ~1.1 ppt and in the southern hemisphere ~0.95 ppt. Since the new data cannot be considered to be less reliable than the old estimate the $PEC_{air\text{-}global}$ should be set to 1 ppt.

A method based on global mass balance was used by the applicant to estimate the atmospheric lifetime, or the residence time of sulfuryl fluoride in the troposphere. In this approach the atmospheric lifetime was defined as the atmospheric burden divided by the emissions (=global sink, at steady-state). It was assumed that the mass of sulfuryl fluoride manufactured (globally during 1992-2000) was equivalent to the mass of sulfuryl fluoride emitted to the atmosphere. The $PEC_{air\text{-}global}$ of 0.5 ppt was used to estimate the atmospheric burden of sulfuryl fluoride. The resultant atmospheric lifetime of sulfuryl fluoride was estimated to be <4.5 years, equivalent to an atmospheric half-life of <3.2 years. Since there are now new measurements on sulfuryl fluoride in air, as mentioned above, as well as new estimates on global emissions of sulfuryl fluoride (provided by the applicant in March 2007) a new mass balance calculation has been performed. The result of this indicates that the atmospheric lifetime for sulfuryl fluoride is 5.2 years, equivalent to a half-life of 3.6 years.

Also the authors of the poster presented in December 2006 presented an estimate of the atmospheric lifetime for sulfuryl fluoride which was around 14 years. This value had been calculated using simple 2-box and 4-box models. This approach relied on the use of the different measured values in the northern and southern hemispheres, and generally known mixing rates of air between the hemispheres, and the assumption that all sulfuryl fluoride is released in the northern hemisphere, to calculate what the atmospheric lifetime would need to be in order to result in the observed ratio of concentrations between the hemispheres. It is an alternative indirect approach to determining the atmospheric lifetime.

At present, RMS cannot conclude which of the two approaches to calculate the atmospheric lifetime for sulfuryl fluoride that generates the most reliable estimate. Therefore the general conclusion must be that the atmospheric lifetime of sulfuryl fluoride, at present, seems to be somewhere in the range of 5 to 14 years, equivalent to a half-life between 4 to 10 years.

Since the estimated atmospheric lifetimes are greater than typical intra- and inter-hemispheric atmospheric mixing times (0.5 years), it was assumed that sulfuryl fluoride will be uniformly distributed throughout the troposphere. Therefore the predictions (for all environmental compartments) obtained from the modelling at the global scale environment are the most useful and relevant since regional or local scenarios will either be very brief or even of non-existent nature.

Degradation and loss processes in air

It is expected that direct photolysis is not a significant contributor to the degradation of sulfuryl fluoride in the troposphere. At higher altitudes in the atmosphere (i.e. stratosphere), where the amount of shorter wavelength radiation is much greater, direct photolysis of sulfuryl fluoride

will likely become a significant degradation route. Reactions with photochemically generated species (e.g. OH radicals) are estimated to be of no importance as loss processes for sulfuryl fluoride in the troposphere.

One loss process of expected importance for sulfuryl fluoride in the atmosphere is hydrolysis in ocean waters. In fugacity modelling it was concluded that even though the predicted steady-state concentration in global surface waters is very low (1.3×10^{-11} mg/l) the model predicted that >70% of the sulfuryl fluoride removed globally will be via this compartment. The rate of degradation of sulfuryl fluoride in ocean waters will be determined by the air-water transfer velocity because of the rapid rate of hydrolysis once it enters the water compartment.

Global warming potential and CO_2 equivalent emissions of sulfuryl fluoride

The global warming potential (GWP) for sulfuryl fluoride over a 100 year time horizon was estimated to be <378. The impact of a gas on the energy balance of the atmosphere is a function of its intrinsic radiative transfer properties and atmospheric lifetime (described by its GWP) and the magnitude of the emissions of that gas to the atmosphere. Since GWP relates the radiative forcing of a gas to CO_2 on a kg per kg basis, multiplying the annual emissions of sulfuryl fluoride by its GWP convert these emissions to CO_2 equivalents. The fraction of CO_2 equivalent emissions of sulfuryl fluoride (from 1992-2000) to total CO_2 equivalent emissions (from 1990) of all gases expected to have significant emissions in the 21st century, was estimated to be <0.004%. The fraction of CO_2 equivalent emissions of sulfuryl fluoride relative to CO_2 alone was estimated to be <0.010%. In conclusion, CO_2 equivalent emissions of sulfuryl fluoride represent a negligible amount of the total current and probably also future emissions of radiatively active gases. When new reliable (and/or verified) data on the atmospheric lifetime of sulfuryl fluoride is available the applicant will make a new estimate of the GWP but until then the present estimate is considered to be acceptable. A new estimate of the GWP will probably influence the size of the fraction of CO_2 equivalent emissions of sulfuryl fluoride to total CO_2 equivalent emissions but so will also changes in total CO_2 emissions since 1990. Therefore RMS considers the current estimate of the contribution of sulfuryl fluoride compared to other CO_2 equivalent emissions to be acceptable at this point in time.

Ozone depletion- and tropospheric ozone formation potential

Sulfuryl fluoride is not expected to have any potential to deplete stratospheric ozone since it does not contain any chlorine, bromine, or iodine atoms. Since phototransformation processes in the troposphere have been shown to be of minor importance for sulfuryl fluoride there are strong indications that sulfuryl fluoride will not contribute to the formation of tropospheric ozone.

Acidification potential

In order to assess the acidification potential of sulfuryl fluoride its emissions (mean yearly average value 1992-2000) were converted to sulphur equivalent emissions and compared to data on global anthropogenic sulphur emissions. The contribution of sulfuryl fluoride to the total anthropogenic sulphur emissions was found to be <0.001 %.

A similar approach was used when estimating the possible impact of HF (hydrogen fluoride) formed from sulfuryl fluoride. A worst-case estimate assuming quantitative transformation of sulfuryl fluoride to HF was compared with total potential loading of HF from anthropogenic

sources and indicated that the fraction originating from sulfuryl fluoride would be approximately 0.2%.

As known anthropogenic emissions of sulphur and nitrogen producing acid precipitation and deposition are several orders of magnitude higher than the potential impact of sulphate and HF from sulfuryl fluoride, it can be concluded that the contribution of sulfuryl fluoride to acid deposition, or acid precipitation will most likely be of marginal importance.

2.2.2.2. Fate and behaviour in water

Sulfuryl fluoride will not be released to the aquatic environment and will not directly impact surface water bodies because of its physical properties and use patterns. The fugacity modelling performed simulating the global environment, predicted that ≤0.007% of released sulfuryl fluoride will partition to the water phase. The main route of entry to surface waters is expected to be through partitioning with the air phase. The predicted concentration in surface waters (PEC_{SW}) was estimated to be 1.3×10^{-11} mg/l for the global scenario.

Hydrolytic degradation in surface waters is expected to be the most important loss process of sulfuryl fluoride in the aquatic compartment. The rate of hydrolysis has been shown to be very rapid in alkaline solutions but slower in neutral and acidic solutions. At pH 2, pH 7 and pH 9 the half-lives were estimated to be 5.3 days, 4.6 hours and 2.8 minutes, respectively at 25°C. For comparison, the half-life at 12 °C and pH 7 was estimated to 12.7 hours. Surface waters in a global perspective are represented by ocean waters and at representative conditions for this environmental compartment (pH 8.1 and 17 °C) the hydrolysis rate was estimated to be 41 minutes.

2.2.2.3. Fate and behaviour in soil

Sulfuryl fluoride will not be directly released to soil. Due to its physical properties and use pattern it will be a gas under normal environmental conditions and the general exposure to soil is expected to be very limited. Fugacity modelling has shown that of the total amount of sulfuryl fluoride released globally $<10^{-6}$ % will partition to soil and the predicted concentration in soil ($PEC_{soil\text{-}global}$) is 1.5×10^{-13} mg/kg. Since there is no direct or long term exposure to soil, no experimental data was submitted on the rate and route of degradation or adsorption/desorption behaviour of sulfuryl fluoride in soil.

2.2.2.4. Effects assessment and risk characterisation

There is no direct release of sulfuryl fluoride to water and exposure of the aquatic environment of sulfuryl fluoride is expected to be very limited because of its physical properties and use patterns. Fugacity modelling simulating the global environment, predicted that >99.99% of released sulfuryl fluoride will partition into the air phase and ≤0.007% will partition to the water phase and the $PEC_{SW\text{-}global}$ was estimated to be 1.3×10^{-11} mg/l. A worst case local surface water concentration ($PEC_{SW\text{-}local}$) has been estimated to 5.2×10^{-5} mg/l. Only those studies required enabling the active substance to be classified and labelled (i.e. acute toxicity tests on one fish species, one invertebrate species and a green algal species) have been conducted and for those a risk characterisation has been done. The calculated ratios between $PEC_{SW\text{-}global}$ and $PEC_{SW\text{-}local}$ and the predicted no effect concentration for the aquatic environment ($PNEC_{aqua}$) were 2.1×10^{-8} and 0.084 respectively. These results indicated that the risk posed to aquatic organisms from the proposed use of sulfuryl fluoride is low.

Since hydrolysis is considered to be an important route of degradation for sulfuryl fluoride in natural surface waters, an assessment of the risk posed to aquatic organisms by the formation of hydrolysis products was performed. The result showed that the risk posed to aquatic organisms is low when exposed to hydrolysis products which have accumulated in the water during ten years.

No data was submitted on the effects on terrestrial organisms of sulfuryl fluoride. Because of its physical properties sulfuryl fluoride will be a gas under normal environmental conditions. Fugacity modelling has also shown that of total amount of sulfuryl fluoride released globally, $<10^{-6}$% will partition to soil and the predicted concentration in soil ($PEC_{soil\text{-}global}$) is 1.5×10^{-13} mg/kg.

The most likely risk posed to terrestrial wildlife is inhalation of sulfuryl fluoride close to a building during fumigation and venting. There is, however no guidance on how to perform such a risk characterisation and therefore the estimated PEC/PNEC ratio for this scenario must be seen as a very approximate way of assessing the risk. A potential risk was identified since the PEC/PNEC ratio was slightly more than one (<1.3). But due to the worst case nature of the assessment (e.g. conservative assessment factor, no established effect at the selected toxicity data value, very low probability for the scenario) sulfuryl fluoride is not considered to be a substance of concern for the terrestrial compartment.

The PEC/PNEC ratio for the global, long term exposure scenario indicated that there is very little risk for effects on wildlife when exposed to maximum background concentrations ($PEC_{air\text{-}global}$) of sulfuryl fluoride.

2.2.3. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. DECISION

3.1. Background to the Decision

The proposed use for sulfuryl fluoride as PT18 is as fumigant to control stored product insect pests. The treatments are intended for fumigation of emptied food processing facilities. Prior to fumigation all machinery has to be run out to complete emptiness and then dry cleaned. All stored finished products have to be removed. No food materials should be left in areas to be fumigated. The effectiveness of sulfuryl fluoride against target organisms has been satisfyingly shown in a number studies.

Sulfuryl fluoride is considered a non-specific target poison acting by disrupting the glycolysis and citric acid cycles, thereby depriving the insect of the necessary energy for survival. Since sulfuryl fluoride is a gas it penetrates the pest's body through inhalation in actively respiring life stages or diffusion into the egg. Sulfuryl fluoride is broken down within the insect to the active fluoride anion which disrupts the glycolysis and fatty acid cycles. It has been suggested that inhibition of magnesium enzyme systems is the inhibitory action within the glycolysis cycle. The effectiveness of sulfuryl fluoride is dependent on the concentration in air at the site of the pest, the exposure time and the physiological response of the pest species and life stage.

Sulfuryl fluoride is a colourless gas with a boiling point of -54 °C and a melting point of -137 °C. Its vapour pressure is 1.6 MPa at 20 °C and the relative vapour density is 3.5 (air = 1). Its solubility in water was determined to be 1.04 g/l at 20 °C. The representative biocidal product named ProFume solely consists of technical sulfuryl fluoride (typical purity 99.8%). Since sulfuryl fluoride is non-flammable, non-explosive and has no oxidizing properties no risks has been identified for the use of sulfuryl fluoride in the biocidal product, based on the physical and chemical properties.

Acceptable method of analysis for the technical sulfuryl fluoride is available where gas chromatography with column switching technique and thermal conductivity detection is used. Residues of sulfuryl fluoride can be determined in air and body fluids by ion-selective electrode. No further method was submitted for soft tissues since there is little storage of fluoride in this matrix. No requirements are made for methods in soil, water or food and feeding stuff due to the physical/chemical properties of sulfuryl fluoride and the proposed use as an insecticide in emptied food processing facilities. Nevertheless, analysis methods for food stuffs have been submitted since they are available for 91/414/EEC evaluation and these have been included in the present report as additional information in case of accidental fumigation during a food processing fumigation.

A data package was presented, providing information on toxicity and metabolism of sulfuryl fluoride. Sulfuryl fluoride is a gas and therefore the exposure to this substance is via inhalation. The classification for sulfuryl fluoride is R23 "toxic by inhalation". Acute exposure to sulfuryl fluoride at a high concentration level can be lethal as indicated by both human and animal data. Sulfuryl fluoride is not toxic after dermal exposure and does not act as a dermal irritant. The studies of eye irritation and skin sensitization have been waived but indirect evidence from other conducted animal studies or from the experiences of using this substance showed that sulfuryl fluoride is unlikely to be a skin sensitizer or an eye irritant. Sulfuryl fluoride is not genotoxic *in vivo* by micronucleus test but positive *in vitro* in clastogenicity and mutagenicity tests in mammalian cells. Sulfuryl fluoride is not carcinogenic in rat and mouse or toxic to reproduction. Short-term or chronic exposure to sulfuryl fluoride causes systemic effects of

brain vacuolation in all tested species at different degrees and dose levels, renal failure in rat and decreased body weight. The local effect is irritation in respiratory tract. Neurotoxic effects are minor slowing of some evoked potentials (visual, auditory and somatosensory) at short-term exposure.

An acceptable operator exposure concentration (AOEC) for sulfuryl fluoride is set to 3 ppm for bystanders, based on an acute neurotoxicity study. The NOEL/NOAEL for this study is 300 ppm, the top dose tested. A safety assessment factor of 100 is applied. For operators the AOEC is based on a subchronic study and is set to 1 ppm. The NOAEL in this study is 30 ppm based on slight vacuolation of the brain at 100 ppm. A safety assessment factor of 100 is applied. However, a limit value, when operators need to leave the area and put on self-contained breathing apparatus (SCBA) is proposed to be set at 3 ppm. The rationales behind this are; the use pattern and the fact that this limit value will not, according to exposure studies performed, result in an exposure that exceeds the AOEC of 1 ppm over a longer period of time. The operator exposure studies were performed under conditions that cover the use applied for in the dossier (use pattern, maximum concentration, maximum target dosage etc.). Results from these studies have also been used for local PEC calculations.

The results from the exposure studies showed an average potential exposure below 1 ppm. For European mills the mean 8 hour TWA was 0.40 ppm. Since these values are averages it is true that the concentration occasionally will be higher for shorter periods. Mandatory use of respiratory protective equipment (SCBA) is therefore essential to ensure that operator exposure is below the limit value level at any fumigation phase. On the other hand, close monitoring of the air concentrations of sulfuryl fluoride in fumigator's working area is essential during fumigation period so fumigators can immediately leave the area and apply SCBA whenever the air concentration is found to be close to 3 ppm.

Exposure data (11 fumigation trials) for bystanders showed that the levels of sulfuryl fluoride were not above 3 ppm at a distance of 10 metres or more from the mill. In conclusion, there is no risk for bystanders to be exposed to sulfuryl fluoride concentrations above 3 ppm at a distance >10 metres from the mill. Therefore, a 10-metre exclusion zone could be proposed for bystanders. Should however the monitored levels of sulfuryl fluoride at distances less than 10 metres from any structure being fumigated indicate that the exclusion zone needs to be expanded outwards this must of course be done. Re-entry to fumigated sites is only allowed after establishing that the local air concentration of sulfuryl fluoride is below 3 ppm by a fumigator.

Biocidal products containing sulfuryl fluoride shall be authorised only for professional use. Due to the hazardous nature of sulfuryl fluoride fumigators must be able to use SCBA if needed. Further, surveillance of the concentrations of sulfuryl fluoride outside the fumigated structure, by use of monitoring equipment, is a prerequisite to ensure safe level of exposure for both operators and bystanders. It can be foreseen that product authorisation will require that the fumigations are performed by users (fumigators) with documented education to ensure that risk mitigation measures are taken.

Fumigation with sulfuryl fluoride used as PT18 is for non-food applications. Therefore all food items not kept in glass, metal bottles, cans or jars with the original manufacturer's air-tight seal package must be removed from the premises to be fumigated. There is further no indirect exposure to sulfuryl fluoride via environment, i.e. via drinking water, plants or livestocks. The setting of ADI or ARfD is considered to be irrelevant for sulfuryl fluoride regarding its application as PT18 (insecticide).

Sulfuryl fluoride is released to the environment during and after fumigation of sealed enclosures. It is expected that sulfuryl fluoride emitted to the atmosphere will remain primarily in the air phase due to its physical properties. This was also supported by fugacity modelling which showed that >99.99% of emissions of sulfuryl fluoride will at equilibrium partition to the atmosphere. The environmental compartment of greatest concern for sulfuryl fluoride is therefore considered to be the atmosphere.

The atmospheric lifetime of sulfuryl fluoride was estimated to be somewhere in the range of 5 to 14 years, equivalent to a half-life between 4 to 10 years. Since the estimated atmospheric lifetimes are greater than typical intra- and inter-hemispheric atmospheric mixing times (0.5 years), it was assumed that sulfuryl fluoride will be uniformly distributed throughout the troposphere. Therefore the predictions (for all environmental compartments) obtained from the modelling at the global scale environment were generally the most useful and relevant since regional or local scenarios will either be very brief or even of non-existent nature.

The Global Warming Potential (GWP) of sulfuryl fluoride was estimated to be <378 (relative to CO_2 and for a 100-year time horizon). Carbon dioxide equivalent emissions (CO_2e) of sulfuryl fluoride represent a negligible amount (<0.004%) of the total current and possibly also future emissions of radiatively active gases. Sulfuryl fluoride will have a negligible contribution to stratospheric ozone depletion and tropospheric ozone formation. The contribution of sulfuryl fluoride to acid deposition, or acid precipitation will most likely be of marginal importance.

Due to the physical properties and use pattern of sulfuryl fluoride it will be a gas under normal environmental conditions and very limited exposure to non-target species is expected. There is further no direct exposure to the aquatic environment or to soil. No risk for the aquatic compartment has been identified. No tests on behaviour in soil or effects on terrestrial organisms have been done. For terrestrial (inhaling) wildlife a potential risk was identified in the immediate vicinity of a fumigated building. However, due to several worst case assumptions and low probability for the scenario, sulfuryl fluoride is not considered to be a substance of concern for the terrestrial compartment.

3.2. Decision regarding Inclusion in Annex I

Sulfuryl fluoride shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 18 (Insecticide), subject to the following specific provisions:

Member States shall ensure that authorisations are subject to the following conditions:

1. Products shall only be sold to and used by professionals trained to use them.

2. Appropriate measures to protect fumigators and bystanders during fumigation and venting of treated buildings or other enclosures must be taken.[5]

3. Labels and/or safety-data sheets of products shall indicate that, prior to fumigation of any enclosure, all food items must be removed.

4. Concentrations of sulfuryl fluoride in remote tropospheric air are monitored.

[5] The concentration of sulfuryl fluoride in 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.

Member States shall also ensure that reports of the monitoring referred to in point (4) are transmitted by authorisation holders directly to the Commission every fifth year starting at the latest after 5 years after the authorisation. The limit of detection for the analysis shall be at least 0.5 ppt (equivalent to 2.1 ng sulfuryl fluoride/m^3 of tropospheric air).

3.3. Elements to be taken into account by Member States when authorising products

No specific elements have been identified.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of sulfuryl fluoride in Annex I to Directive 98/8/EC.

However, when the new monitoring data on sulfuryl fluoride levels in atmospheric air (see competent authority report; Doc II-A section 4.1.2.1) have been published in peer-reviewed literature or when other reliable measurements are available a new estimate of atmospheric lifetime as well as a new estimate on the GWP (global warming potential) of sulfuryl fluoride will be required.

3.5. Updating this Assessment Report

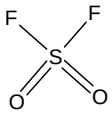
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of sulfuryl fluoride in Annex I to the Directive.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	Sulfuryl fluoride (There is no ISO common name for this substance; the name "sulfuryl fluoride" has been used in the literature but has no official status except as a systematic name.)
Product type and function	Product-type 18. Insecticide (fumigant to control stored product insect pests) in emptied food processing facilities
Rapporteur Member State	Sweden (Competent Authority: Swedish Chemicals Agency, KemI)

Identity

Chemical name (IUPAC)	Sulfuryl fluoride/sulfuryl difluoride
Chemical name (CA)	Sulfuryl fluoride
CAS No	2699-79-8
EC No	220-281-5
Other substance No.	CIPAC No. 757
Minimum purity of the active substance as manufactured (g/kg or g/l)	994 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	There are no relevant impurities in the active substance as manufactured.
Molecular formula	SO_2F_2
Molecular mass	102.1 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	-136.8 °C (purity 99.4 mol%)
Boiling point (state purity)	-54°C ± 1 °C (purity 98.8 %)
Temperature of decomposition	Not required. No decomposition or sublimation occurs at the melting or boiling temperature. It is a gas. According to theoretical assessment the gas itself is considered to be thermally stable up to 1227 °C.
Appearance (state purity)	Colorless gas (purity 98.8%). Odour not determined due to hazardous nature of test substance.
Relative density (state purity)	4.2 g/l at 20 °C and 1 atm, calculated from the Ideal Gas Law

Surface tension	67.5 mN/m (90% saturated solution) (purity 99.8%) at 20 °C
Vapour pressure (in Pa, state temperature)	1.6 MPa at 20 °C (purity 99.35-99.51 mol %)
Henry's law constant (Pa m^3 mol^{-1})	Not required for substances which are gases. Calculated for other purposes as: 158142 Pa m^3 mol^{-1} (1.56 atm m^3 mol^{-1})
Solubility in water (g/l or mg/l, state temperature)	In unbuffered water (pH=2.5): 1.04 g/l at 20 °C (purity 99.8%)
Solubility in organic solvents (in g/l or mg/l, state temperature)	Solvent — Solubility g/l (20 °C) n-heptane 22 xylene 25 1,2-dichloroethane 25 methanol 33 acetone 71 ethyl acetate 59 n-octanol 14
Stability in organic solvents used in biocidal products including relevant breakdown products	Not relevant. The active ingredient is the product.
Partition coefficient (log P_{ow}) (state temperature)	In unbuffered solutions: Log P_{ow} = 0.14, measured at 20 °C
Hydrolytic stability (DT_{50}) (state pH and temperature)	(purity >99%) pH 2, 25 °C: 5.3 days pH 5.9, 25 °C: 3.1 days pH 7, 20 °C: 6.7 hours pH 7, 25 °C: 4.6 hours pH 9, 20 °C: 4.0 min pH 9, 25 °C: 2.8 min
Dissociation constant	Not required - test substance does not reversibly ionize
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	<u>In purified water (pH=2.0)</u> λ (nm) ε (L x mol^{-1} x cm^{-1}) 276 37 <u>In 0.1 M HCl (pH=1.3)</u> λ (nm) ε (L x mol^{-1} x cm^{-1}) 278 61 No absorption maxima >290 nm
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Not determined (in water) due to high vapour pressure
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not determined (in water) due to high vapour pressure
Flammability	Non-flammable and not considered to be auto-flammable
Explosive properties	Not explosive

Classification and proposed labelling

According to the 29th ATP, rev. 19 (Directive 2004/73/EC).	
with regard to physical/chemical data	No classification
with regard to toxicological data	T – Toxic R23 - Toxic by Inhalation R48/20 – Harmful: Danger of serious damage to health by prolonged exposure through inhalation. S1/2 - Keep locked up and out of reach of children. S45 - In case of accident of if you feel unwell, seek medical advice immediately (Show the label where possible) [S60[6] - This material and its container must be disposed of as hazardous waste] S61 - Avoid release to the environment. Refer to special instructions/Safety data sheets. S63 - In case of accident by inhalation: remove casualty to fresh air and keep at rest
with regard to fate and behaviour data	No classification
with regard to ecotoxicological data	N – Dangerous for the environment R50 – Very toxic to aquatic organisms

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	Gas chromatographic method with column switching technique and thermal conductivity detection.
Impurities in technical active substance (principle of method)	The analytical method for determination of impurities is confidential and can be found in Annex of Confidential Data and Information.

Analytical methods for residues

Soil (principle of method and LOQ)	Not applicable.
Air (principle of method and LOQ	Air is drawn through charcoal adsorbent tubes to trap sulfuryl fluoride. Sodium hydroxide (NaOH) is used for desorption and the extract is heated to convert the sulfuryl fluoride to fluoride and sulfate. The fluoride content is measured with an ion-selective electrode and the standard addition technique and used to calculate the amount of sulfuryl fluoride. LOQ is 0.43 mg/m^3 (0.104 ppm)
Water (principle of method and LOQ	Not applicable.
Body fluids and tissues (principle of method and LOQ)	No specific methods were developed for the analysis of residues in body fluids or tissues. Sulfuryl fluoride is rapidly hydrolysed in aqueous conditions such that the

[6] S60: RMS agrees with the applicant that this safety phrase is not suitable for sulfuryl fluoride since the cylinders containing sulfuryl fluoride are recycled and may be used for many years.

	parent material would not be a useful biomarker. Analysis of fluoride in body fluids using ion-selective electrode (ISE) is considered most relevant in this context and the technique is utilized in two submitted published literature studies. No direct LOQ are reported in the studies. No further method was submitted for tissues since there is little storage of fluoride in this matrix.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required due to the use pattern of sulfuryl fluoride as PT18. However, methods for determining sulfuryl fluoride and fluoride ion in various food/feed of plant origin are available due to use of sulfuryl fluoride under 91/414/EC. <u>Fluoride ion</u> Samples (solid samples were first homogenised) were extracted with de-ionised water/ionic buffer and an aliquot of the resulting extract was then centrifuged. The centrifuged extract was then analysed using a fluoride ion specific electrode. LOQ: 0.5-5 mg/kg <u>Sulfuryl fluoride</u> Samples were extracted by blending them in an airtight blender, in the presence of water and the resulting headspace at the top of the blender analysed by GC-ECD, using a GS-Q megabore column. LOQ: 0.004-0.01 mg/kg
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required due to the use pattern of sulfuryl fluoride as PT18.

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	No data submitted. Not relevant.
Rate and extent of dermal absorption:	No data submitted. Not relevant.
Rate and extent of inhalational absorption	Rapid. The absorbed dose was estimated to be 14% at 30 ppm and 11% at 300 ppm based on the actual 'dose received' (radioactivity in urine, faeces and tissues) over a 4-hour exposure period.
Distribution:	^{35}S was found in various tissues. The distribution seems to be non-organ specific. Radioactivity was recovered mainly in tissues at the site of first exposure to the gas.
Potential for accumulation:	Sulfuryl fluoride: No potential for accumulation. Fluoride: Short term, low level or infrequent exposure leads unlikely to any accumulation. Long term, repeated exposures may lead to accumulation of fluoride, primarily in teeth or bones.
Rate and extent of excretion:	^{35}S was rapidly excreted. Primarily excretion is via urine during the 4-hour exposure period. The initial half lives for the radioactivity in plasma and RBC are ~2.5 hours at 30 ppm and 1-2.5 hours at 300 ppm exposures. The terminal half-life of radioactivity was approximately 2.5-fold longer in RBC than in plasma.
Toxicologically significant metabolite	Fluoride ion

Acute toxicity

Rat LD_{50} oral	*Ca*. 100 mg/kg bw (study of low reliability)
Rat LD_{50} dermal	>9599 ppm
Rat LC_{50} inhalation Mouse LC_{50} inhalation	991 ppm, between 400 and 600 ppm.
Skin irritation	Not applicable.
Eye irritation	Not applicable.
Skin sensitization (test method used and result)	Not applicable.

Repeated dose toxicity

Species/ target/critical effect	Rat: irritation in respiratory tract, alveolar histiocytosis, mild hyperplasia in kidney, vacuolation in cerebrum. Dog: irritation in respiratory tract, aggregates of macrophages in alveoli, microscopic dental fluorosis. At higher doses (200 ppm) minimal vacuolation and gliosis of the brain. Rabbit: irritation inrespiratory tract, vacuolation in cerebrum. Mouse: vacuolation in cerebrum.
Lowest relevant oral NOAEL/LOAEL	No reliable data.
Lowest relevant dermal NOAEL/LOAEL	Not applicable.
Lowest relevant inhalation NOAEL/LOAEL	30/100 ppm (mouse)

	20/80 ppm (dog, 20 ppm based on local effect and microscopic dental fluorosis that is not considered relevant in this case; 12-month)
Genotoxicity	No genotoxic risk to humans
Long term toxicity	
Species/target/critical effects:	Rats: chronic progressive glomerular nephrosis and minor lung irritation (2 year combined chronic toxicity and carcinogenicity study) Mice: very slight vacuolation in cerebrum exacerbation of systemic amyloidosis in females (18 months combined chronic toxicity and carcinogenicity study).
Lowest relevant NOAEL/LOAEL	20/80 ppm (rat and mouse) NOEL: 5 ppm based on dental fluorosis (rat). This is considered an adverse effect that is not relevant in this case.
Carcinogenicity	
Species/type of tumour	Non-carcinogenic in rat or mouse.
Lowest dose with tumours	No tumours observed.
Reproductive toxicity	
Species/reproduction target/critical effect	Rat; Reproduction: none Parental: aggregates of alveolar macrophages at 20 ppm. Offspring: ↓ bodyweight gain at 150 ppm.
Lowest relevant-NOAEL	Reproduction: 150 ppm (highest dose tested) Parental: 5 ppm (based on a local effect) Offspring: 20 ppm
Species/developmental target/critical effect	Not teratogenic in rat or rabbit. Rabbit: reduced body weight in dams and offspring at 225 ppm.
Lowest relevant-NOAEL	Developmental: 75 ppm (rabbit) Maternal: 75 ppm (rabbit)
Neurotoxicity / Delayed neurotoxicity	
2-day acute neurotoxicity study in rats	No evoked potentials affected. The NOEL was 300 ppm (highest dose tested).
13-weeks neurotoxicity study in rats	Slowing of visual, auditory and somatosensory evoked potentials

	Mild vacuolation of the brain at 100 ppm NOEL: 30 ppm.
12-month chronic neurotoxicity study in rats	No neurotoxic effects at the highest dose. NOEL: 80 ppm

Other toxicological studies

None

Medical data

Acute exposure: can be lethal. Symptoms: eye and respiratory irritation (These reactions may also relate to the simultaneous use of chloropicrin with sulfuryl fluoride), sore throat and cough, flu-like symptoms (nausea, diarrhea, fever and headache), shortness of breath or respiratory distress.

Summary	Value	Study	Safety factor
ADI (if residues in food or feed)	Not relevant	-	-
AOEC (Operator/Worker), representing AEC_{medium}	1 ppm	Mouse 90 day inhalation study	100
AOEC (Bystander), representing AEC_{acute}	3 ppm	Rat acute neurotoxicity	100
$AEC_{chronic}$ (not used in this risk assessment)	0.4 ppm	Mouse 18 month	100
Drinking water limit	Not relevant	-	-
ARfD (acute reference dose)	Not relevant	-	-

Acceptable exposure scenarios (including method of calculation)

Professional users	Based on the data from structural fumigation trials. Acceptable exposure provided fumigators wearing respiratory protective equipment (self-contained breathing apparatus) when introducing and aerating the gas or in any occasion that air concentration of the gas is above 3 ppm. Under these conditions the long term exposure will not exceed the AOEC of 1 ppm.
Workers (re-entry)	Based on the data from structural fumigation trials. Re-entry for non-fumigation workers is not allowed until the air concentrations of sulfuryl fluoride have been measured and confirmed by the fumigator to be below a limit value of 3 ppm
Non-professional users	Not applicable.
Indirect exposure as a result of use	Appropriate measures to protect bystanders (general population) during fumigation and venting of treated buildings or other enclosures must be taken. The exposure level of sulfuryl fluoride in air shall not exceed 3 ppm.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 2, 25 °C: 5.3 days pH 5.9, 25 °C: 3.1 days pH 7, 25 °C: 4.6 hours (20 °C: 6.7 hours) pH 9, 25 °C: 2.8 min (20 °C: 4.0 min)
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Not applicable.
Readily biodegradable (yes/no)	Not applicable.
Biodegradation in seawater	Not applicable.
Non-extractable residues	Not applicable.
Distribution in water / sediment systems (active substance)	Not applicable.
Distribution in water / sediment systems (metabolites)	Not applicable.

Route and rate of degradation in soil

Mineralization (aerobic)	Not applicable.
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Not applicable.
Field studies (state location, range or median with number of measurements)	Not applicable.
Anaerobic degradation	Not applicable.
Soil photolysis	Not applicable.
Non-extractable residues	Not applicable.
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	Not applicable.
Soil accumulation and plateau concentration	Not applicable.

Adsorption/desorption

Ka, Kd Ka_{oc}, Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	K_{OC} 0.566 l/kg (theoretical estimate of the organic carbon-water partitioning)

Fate and behaviour in air

Direct photolysis in air	T½ (estimated): >2 years at the surface of the earth T½ (estimated): >1.1 years at the top of the troposphere
Quantum yield of direct photolysis	Not determined (assumed as 1 in above estimate)
Photo-oxidative degradation in air	*k (rate constant)* = $<<10^{-12}$ cm^3/molecule sec
Volatilization	Not applicable; permanent gas

Monitoring data, if available

Soil (indicate location and type of study)	None
Surface water (indicate location and type of study)	None
Ground water (indicate location and type of study)	None
Air (indicate location and type of study)	Local scenario: Monitoring of air concentrations at various positions around mills during fumigation and venting processes (trials) has yielded maximum 24-hour time weighted average concentrations for a range of distances from the mill. The 90th percentile of 1.51 ppm (6.3 mg/m^3) at 5 metres was taken to represent the "worst-case" scenario of maximum exposure for any individuals in the vicinity of the mill. Global scenario: Sulfuryl fluoride has been identified in remote atmospheric air samples at concentrations of approx. 1.1 ppt in the northern hemisphere and approx. 0.95 ppt in the southern hemisphere.

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity (mg/l)
Fish			
Fish (*Brachydanio rerio*)	96 h	LC_{50}	0.89
Invertebrates			
Invertebrate (*Daphnia magna*)	48 h	EC_{50} (immobilisation)	0.62
Algae			
Algae (*Selenastrum capricornutum*)	72 h	E_rC_{50} (E_bC_{50} (growth inhibition)	1.13 0.58)
Microorganisms			
Not determined.			

Effects on earthworms or other soil non-target organisms

Acute toxicity to ……..……..	Not applicable.
Reproductive toxicity to……	Not applicable.

Effects on soil micro-organisms

Nitrogen mineralization	Not applicable.
Carbon mineralization	Not applicable.

Effects on terrestrial vertebrates

Acute toxicity to mammals	NOAEL ≥300 ppm (inhalation study on rat, 6-hour exposures within 30 hours).
Acute toxicity to birds	Not applicable.
Dietary toxicity to birds	Not applicable.
Reproductive toxicity to birds	Not applicable.

Effects on honeybees

Acute oral toxicity	Not applicable.
Acute contact toxicity	Not applicable.

Effects on other beneficial arthropods

Acute oral toxicity	Not applicable.
Acute contact toxicity	Not applicable.
Acute toxicity to ……..	Not applicable.

Bioconcentration

Bioconcentration factor (BCF)		Not applicable.
Depuration time	(DT_{50})	Not applicable.
	(DT_{90})	Not applicable.
Level of metabolites (%) in organisms accounting for > 10 % of residues		Not applicable.

Chapter 6: Other End Points	None

Appendix II: List of Intended Uses

Field of use envisaged

Fumigant to control stored product insect pests (SPIs) in emptied food processing and storage facilities including processing of cereals (e.g. breakfast cereal), flour and semolina based products (e.g. biscuits, cakes, pasta), chocolate confectionary, dried fruit and tree nuts.

User

Professional use only

Product name

ProFume

(The trade name 'ProFume' is also used for applications under Directive 91/414/EEC. Under Directive 98/8/EC the tradename 'Vikane' is used for PT8. Vikane and ProFume are identical products.)

Organisms controlled

Common Name(s)	Scientific Name
Mediterranean flour moth Flour moth Mill moth	*Ephestia kuehniella*
Tropical warehouse moth Almond moth Dried fruit moth	*Ephestia cautella*
Indian meal moth	*Plodia interpunctella*
Rust red flour beetle Red flour beetle	*Tribolium castaneum*
Confused flour beetle	*Tribolium confusum*
Saw toothed grain beetle	*Oryzaephilus surinamensis*
Warehouse beetle	*Trogoderma variabile*
Biscuit beetle Drug store beetle	*Stegobium paniceum*
Hide beetle Leather beetle	*Dermestes maculatus*

Formulation

Type: Gas

Concentration of a.s.: 998 g/kg (typical value). Min. purity: 994 g/kg

Application

Method, kind: Fumigation. Disinfestation of insects from emptied food processing structures and storage areas. This allows penetration of the fumigant into all areas where insects may be present e.g. within the fabric of the building (floors, walls, ceilings), machinery and packaging material.

Prior to fumigation all machinery is run out to complete emptiness and then dry cleaned. All storage areas and silos are emptied. All stored finished products are removed. No food materials are left in areas to be fumigated.

The structure has to be made as gas tight as possible by sealing all openings (e.g. windows, doors). ProFume is then introduced and following the required exposure period the structure is then aerated.

Number, min – max: Once to achieve disinfestation. Repeated application may only be needed if reinfestation occurs.

Interval between applications (min): Dependent on whether reinfestation occurs.

Applied amount per treatment

Gram as/l, min – max: not applicable

Water l/m^2, min - max: not applicable

Dosage, min – max: The dosage is the product (P) of concentration (C) and exposure time (T) and abbreviated CTP (or Ctp) and measured in g·h/m^3 (also written as g-h/m^3). The maximum concentration is 128 g/m^3 and the maximum target dosage for ProFume is 1500 g·h/m^3. The dosage is dependent on the pest species, the life stage and the temperature. Increasing the temperature reduces the dosage required for all pest life stages.

For fumigation to control stored product insects, a computer programme (Fumiguide) has been developed to be used for the coordination of fumigant rates with the parameters of temperature at the site of the pest, exposure period, and fumigant loss rate measured as half-loss-time (HLT). The HLT is a measure of gas confinement as is defined as the time in hours taken for the concentration of sulfuryl fluoride to reduce by 50%. All fumigations with ProFume in the EU will have to be monitored.

Laboratory chamber fumigations support the proposed dosages included in the Fumiguide and the label recommendation for control of all life stages of the following SPIs: *Ephestia kuehniella, Ephestia cautella, Plodia interpunctella, Tribolium castaneum, Tribolium confusum, Oryzaephilus surinamensi*s, *Trogoderma variabile, Stegobium paniceum and Dermestes maculatus*. The Fumiguide has been developed as a global tool covering a wide range of insect pest species. Only those key insect pests relevant to the EU which are supported by effectiveness data, are listed on the proposed label.

Many dosage options are possible depending on the various parameters which are used. However a calculated dosage must not exceed the maximum target of 1500 g h/m^3. Examples of the dosages derived from the Fumiguide for all life stages of each of the SPIs included on the proposed label are given below.

Parameters: Half loss time = 12 hours, exposure time = 24 hours, temperature = 25^o C, structure volume 20,000 m^3.

Insect species	Dosage g h/m^3	KG Product
Mediterranean flour moth (*Ephestia kuehniella*)	609	939
Indian meal moth (*Plodia interpunctella*)	509	784
Rust red flour beetle (*Tribolium castaneum*)	1127	1737
Confused flour beetle (*Tribolium confusum*)	588	906
Warehouse beetle (*Trogoderma variabile*)	751	1156

Remarks

Do not apply when temperature at the site of the pest activity is below 10 °C. This temperature may be measured at the slab foundation, sub-floor or wherever the coolest part of the fumigation site may be.

Appendix III: List of studies

Data protection is claimed by Dow AgroSciences in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed Y/N" column of the tables below. For studies marked Y(i) data protection is claimed under Article 12.1(c) (i), for studies marked Y(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other MS of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Many of the study reports listed below were submitted already for Annex I listing of sulfuryl fluoride/Vikane as PT8 (wood preservative). In the second column of the tables below it is therefore indicated whether the study in question was submitted for the first time for the Annex I listing of sulfuryl fluoride/ProFume as PT18 or not.

Data Owner:	D = Dow AgroSciences
	P= Public domain

List of studies for the active substance related endpoints (sorted by author)

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.10/01	N	Albee, R. R., Eisenbrandt, D.L Mattisson, J. L. Streeter, C. M.	Sulfuryl Fluoride (Vikane*) Induced Incapacitation In Rats	Dow Chemical Company, Midland	Y	N	Y	Y (ii)	D	K-016399-018	September 1983

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.9/01	N	Albee, R.R., Spencer, P.J, Bradley, G.J.	Sulfuryl Fluoride: Electrodiagnostic, FOB and Motor Activity Evaluation of Nervous System Effects from Short-term Exposure	Toxicology Research Laboratory, The Dow Chemical Company, Midland, USA	Y	N	Y	Y (i)	D	K-016399-045	May 1993
2.7 2.8	N	Ammons, R.W.	Vikane Product Release, Lot number 874	The Dow Chemical Company	N	N	N	Y (ii)	D	K-016399-037	February 1990
2.7 2.8	N	Anon	Vikane Analysis – K-16399-018	The Dow Chemical Company, Midland, Mi, USA	N	N	N	Y (ii)	D	K-16399-018	April 1980
6.1.1	N	Anon	The Acute Oral Toxicity to Vikane Administration of Single Doses to Male Rats, Female Rats and Guinea Pigs	Dow Chemical Company, Midland	N	N	Y	Y (ii)	D	None	October 1959
6.1.3/01	N	Anon	The Acute Vapor Toxicity Of Vikane As determined on Male and Female Rats	Dow Chemical Company, Midland	N	N	Y	Y (ii)	D	None	October 1959
6.3.1	N	Anon	Short Term Dietary Feeding Study of Commercial Laboratory Diet Fumigated with Vikane	Dow Chemical Company, Midland	N	N	Y	Y (ii)	D	None	October 1959
6.5/03	N	Anon	The Chronic Vapor Toxicity of Vikane as Determined on Laboratory Animals	Dow Chemical	N	N	Y	Y (ii)	D	None	October 1959

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
4.3/01	Y	Barnekow, D.E.,	Evaluation of the Extraction Efficiency of the Direct Diffusion Fluoride-Ion Selective Probe Analysis Method by Direct Comparison to the Total Fluoride Neutron Activation Analysis Technique	Regulatory Laboratories-Dow AgroSciences, Indianapolis, Indiana, USA and Analytical Sciences, The Dow Chemical Company, Midland, Michigan, USA	N	N	N	Y (ii)	D	GH-C 5396	June 2002
4.2b/06	N	Barnekow, D.E., Foster, D.R.	Interim Report – Storage Stability of Sulfuryl Fluoride on SKC 1 g Anasorb CSC Tubes at Ambient and Frozen Temperature Conditions	Regulatory Laboratories-Indianapolis Lab, Dow AgroSciences, Indiana, USA	Y	N	N	Y (ii)	D	990040.01	June 2002

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
4.2b/05	N	Barnekow, D.W., Byrne, S.L., Foster, D.R.	Determination of Exposure Potential to Workers and Atmospheric Concentrations of Sulfuryl Fluoride During and Following Fumigation of Mills Using ProFume – North America 2002	Paragon Research Services, Fresno, CA, USA and MVTL Laboratories, New Ulm, MN, USA and Reg. Laboratories-Indianapolis Lab, Dow AgroSciences LLC, Indianapolis, IN, USA	Y	N	N	Y (ii)	D	020039	June2002
4.2b/04	N	Blaschke, U.	Sulfuryl Fluoride, Determination of Atmospheric Concentrations of Sulfuryl Fluoride and Occupational Exposure of Fumigators during the structural Fumigation of a Mill using ProFume Germany 2002	Huntingdon Life Sciences, Ltd, Huntingdon, UK	Y	N	N	Y (ii)	D	DOS 299/023404	July 2002
6.1.2	N	Bradley, G. J Landry, T. D. Battjes, J. E. Quast, J. F.	Sulfuryl Fluoride: Four-Hour Dermal Vapor Exposure in Fischer 344 Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-036 K-16399-36 K-016399-036A K-0L6399-036B	November 1990

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.1.4/02	N	Bradley, G. J Landry, T. D. Battjes, J. E. Quast, J. F.	Sulfuryl Fluoride: Four-Hour Dermal Vapor Exposure in Fischer 344 Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-036 K-16399-36 K-016399-036A K-0L6399-036B	November 1990
6.8.2	N	Breslin, W. J. Liberacki, A. B. Kirk, H. D. Bradley, G. J. Crissman, J. W.	Sulfuryl Fluoride: Two-Generation Inhalation Reproduction Study in Sprague-Dawley Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-042	January 1992
6.12.2	N	Burns,C.J., Maurissen,J.P., Eisenbrandt,D. L.	Review of Publication: Health Effects Associated With Sulfuryl Fluoride and Methyl Bromide Exposure Among Structural Fumigation Workers. Calvert,G.M., Mueller,C.A., Fajen,J.M., Chrislip,D.W., Russo,J., Briggle,T., Fleming,L.E., Suruda,A.J., Steenland,K. Amer J. Public Health **: 1774-1780, 1998	The Dow Chemical Company, Midland, Michigan, USA	N	N	N	N	D	P12	July 2002

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
7.1.1.1.1 /01	N	Cady, G.H., Misra S.	Hydrolysis of Sulfuryl Fluoride	Department of Chemistry, University of Washington, Seattle	N	Y	N	N	P	Inorganic Chemistry, Vol. 13, No. 4, 1974	April 1974
2.7 2.8	N	Calhoun, D.A., Omealia, N	Analysis for Cylinders of Vikane / for Teratology Studies	Analytical R&D, The Dow Chemical Company, Midland, Mi, USA	N	N	N	Y (ii)	D	K-016399-025/K-16399-(14)	July 1987
2.7 2.8	N	Campbell, R.A.	Composition Report, Vikane UDS Assay	The Dow Chemical Company	N	N	N	Y (ii)	D	GT-45-91	May 1991
3.1.2, 3.3.1, 3.4.2, 3.5, 3.7, 3.9, 3.13	N	Comb, A.L.	Determination of Physico-Chemical Properties for Sulfuryl Fluoride	Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, PE28 4HS, England	Y	N	N	Y (ii)	D	NAFST430	June 2001

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
4.3/02	Y	Creasy, S.R., Hartsell, P.L., Hurley, J.M., Carmona, L.M., Byrne, S.L.	Determination of Residues of Sulfuryl Fluoride in Dried Fruit and Tree Nuts by Gas Chromatography with Electron Capture Detection	Dow AgroSciences, Indianapolis, In, USA	N	N	N	Y (ii)	D	GRM 01.12	July 2001
4.3/03	Y	Creasy, S.R., Hartsell, R.L., Hurley, J.M., Mukker, G.K., Bunnell, J., Byrne, S.L.	Determination of Residues of Sulfuryl Fluoride as Fluoride in Dried Fruit and Tree Nuts Using a Fluoride-Selective Electrode with a Double Known Addition Calibration Technique.	DFA of California, Fresno, Ca, USA	N	N	N	Y (ii)	D	GRM 01.11	June 2001
A4.3/04	Y	Davis, B.	Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 01.12-Determination of Residues of Sulfuryl Fluoride in Dried Fruit and Tree Nuts by Gas Chromatography with Electron Capture Detection	Minnesota Valley Testing Laboratories, New Ulm, Minnesota, USA	Y	N	N	Y (ii)	D	010098	March 2002b

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
A4.3/05	Y	Davis, B.	Independent Laboratory Validation of Dow AgroSciences LLC Method 'Residue Method Validation for the Determination of Fluoride Anion in Corn, Wheat, Corn Oil and Flour,' as included in Lab Report Code: 011057, Appendix A, 'Magnitude of the Terminal Fluoride Ion Level in Cereal Grain Commodities Fumigated with Sulfuryl Fluoride'.	Minnesota Valley Testing Laboratories, New Ulm, Minnesota, USA	Y	N	N	Y (ii)	D	010115	February 2002a
A4.3/06	Y	Davis, B.	Independent Laboratory Validation of Dow AgroSciences LLC Method 'Determination of Residues of Sulfuryl Fluoride in Corn, Wheat and Rice Commodities by Gas Chromatography with Electron Capture Detection,' as included in Lab Report Codes: 0011057, Appendix B, 'Magnitude of the Terminal Fluoride Ion Level in Cereal Grain Commodities Fumigated with Sulfuryl Fluoride'	Minnesota Valley Testing Laboratories, New Ulm, Minnesota, USA	Y	N	N	Y (ii)	D	010114	March 2002c

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
A4.3/07	Y	Davis, B.	Independent Laboratory Validation of Dow AgroSciences LLC Method 'Determination of Residues of Sulfuryl Fluoride in Corn, Wheat and Rice Commodities by Gas Chromatography with Electron Capture Detection,' as included in Lab Report Codes: 0011057, Appendix B, 'Magnitude of the Terminal Fluoride Ion Level in Cereal Grain Commodities Fumigated with Sulfuryl Fluoride' AMENDED	Minnesota Valley Testing Laboratories, New Ulm, Minnesota, USA	Y	N	N	Y (ii)	D	010114	June 2003
A4.3/08	Y	Davis, B.	Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 01.11 – Determination of Residues of Sulfuryl Fluoride as Fluoride in Dried Fruit and Tree Nuts Using a Fluoride-Selective Electrode with a Double Known Addition Calibration Technique	Minnesota Valley Testing Laboratories (MVTL, Inc.), New Ulm, Nn. USA	Y	N	N	Y (ii)	D	010099	April 2002

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.10/03	N	Eisenbrandt, D. L. Williams, D. M. Albee, R. R. Streeter, C. M.	Sulfuryl Fluoride (Vikane* Gas Fumigant): An Ultrastructural Assessment of the Lungs of Rats Exposed to High Concentrations of Sulfuryl Fluoride	Dow Chemical Company, Midland	Y	N	Y	Y (ii)	D	HET K-016399-023	October 1987
6.3.3/01 and 6.3.3/04	N	Eisenbrandt, D.L., Nitschke, K.D., Streeter, C.M. & Wolfe, E.L.	Sulfuryl Fluoride (Vikane* Gas Fumigant): 2-Week Inhalation Toxicity Probe with Rats and Rabbits	Dow Chemical, Midland	Y	N	Y	Y (ii)	D	None	April 1985
6.12.2	N	Eisenbrandt,D. L., Burns, C., Hanley,T.R., Marable,B., Marty,S., Maurissen,J., Wright,J.	A Critical Review of Scientific Publications Related to Fluoride and a Response to Comments on Risk Assessment	Regulatory Laboratories, Dow AgroSciences, Indianapolis, Indiana, USA	N	N	N	N	D	GHC-5496	August 2002

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
3.11, 3.15 3.16	N	Ghaoui, L.	Flammability , Oxidizing and Explosive Properties of Sulfuryl Fluoride	Dow AgroSciences , Formulations Science and Technology Laboratory, Indianapolis, Indiana, USA	N	N	N	Y (ii)	D	NAFST594	September 2002
3.4.3	N	Ghaoui, L.H., Thornburgh S.	Nuclear Magnetic Resonance Study for Sulfuryl Fluoride	Dow AgroSciences, Indianapolis	N	N	N	Y (ii)	D	FOR00006	August 2000
6.6.4	N	Gollapudi, B. B. McClintock, M. L. Nitschke, K. D.,	Evaluation of Sulfuryl Fluoride in the Mouse Bone Marrow Micronucleus Test (in vivo)	Dow Chemical Company, Midland	Y	N	Y	Y (ii)	D	TXT: K-016399-033	February 1990
6.6.3/01	N	Gollapudi, B. B. McClintock, M. L. Zempel, J. A.	Evaluation of Sulfuryl Fluoride in the Rat Hepatocyte Unscheduled DNA Synthesis (UDS) Assay	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-043	October 1991
6.6.1/01	N	Gollapudi, B. B. Samson, Y. E. Zempel, J. A.	Evaluation of Sulfuryl Fluoride in the Ames Salmonella/Mammalian-Microsome Bacterial Mutagenicity Assay	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	TXT:K-016399-037	August 1990

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.6.2	N	Gollapudi, B.B., Linscombe, V.A., Jackson, K.M., DeLisle, T.H., Krieger, S.M., Rick, D.L.	Evaluation of Sulfuryl Fluoride in an In Vitro Chromosomal Aberration Assay Utilizing Rat Lymphocytes	Toxicology & Environmental Research and Consulting, Dow Chemical Company, Midland, USA	Y	N	N	Y (ii)	D	001133	May 2002
6.6.3/02	N	Gollapudi, B.B., Linscombe, V.A., Schisler, M.R., DeLisle, T.H., Krieger, S.M., Rick, D.L.	Evaluation of Sulfuryl Fluoride in the Mouse Lymphoma (L5178Y TK +/-) Forward Mutation Assay	Toxicology & Environmental Research and Consulting, Dow Chemical Company, Midland, USA	Y	N	N	Y (ii)	D	001144	May 2002
6.10/02	N	Gorzinski, S. J. Streeter, C. M.	Effect of Acute Vikane* Exposure on Selected Physiological Parameters in Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET K-016399-021	November 1985

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
4.2d/02	N	Hall, L.L., Smith, F.A., De Lopez, O.H., Garner, D.E.	Direct Potentiometric Determination of Total Ionic Fluoride in Biological Fluids.	Clinical Chemistry, 18/12, 1455-1458 (1972)	N	Y	N	N	P	None	1972
6.8.1/02A	N	Hanley, T. R., Calhoun, L. L. Kociba, R. J., Cobel-Geard, S.R., Hayes, W.C., Ouellette, J.H., Scherbarth, L.M., Sutter, B.N., John, J.A.	Vikane*: Inhalation Teratology Study in Rats and Rabbits	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET K-16399-(15)	October 1981

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.8.1/02B	N	Hanley, T. R., Calhoun, L. L. Kociba, R. J., Cobel-Geard, S.R., Hayes, W.C., Ouellette, J.H., Scherbarth, L.M., Sutter, B.N., John, J.A.	Vikane*: Inhalation Teratology Study in Rats and Rabbits	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET K-16399-(15)	October 1981
6.8.1/01A	N	Hanley, T.R., Calhoun, L.L., Cobel-Geard, S.R., Hayes,W.C., Murray, J.S., Kociba,R.J., John,J.A.	Vikane: Probe Teratology Study in Fischer 344 Rats and New Zealand white Rabbits	The Dow Chemical Company	N	N	Y	Y (ii)	D	HET K-16399-(14)	November 1980

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.8.1/01B	N	Hanley, T.R., Calhoun, L.L., Cobel-Geard, S.R., Hayes,W.C., Murray, J.S., Kociba,R.J., John,J.A.	Vikane: Probe Teratology Study in Fischer 344 Rats and New Zealand white Rabbits	The Dow Chemical Company	N	N	Y	Y (ii)	D	HET K-16399-(14)	November 1980
2.7 2.8	N	Hartl, P.	Analytical Data Sheet: 98-412, Lot no. 880329 752	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	89-412	December 1989
2.7 2.8	N	Harvey, K., Ammons, R.W.	Vikane Product Release, Lot number 408	The Dow Chemical Company	N	N	N	Y (ii)	D	K-016399-022/K-016399-025	September 1983
4.2b/02	N	Huff, D.W; Murphy, P.G	Sulfuryl Fluoride: Re-validation of air monitoring method HEH2.12-38-26(6)	DowElanco, Indianapolis	N	N	N	Y (i)	D	HEH 174	November 1995
4.2b/03	N	Jones, G.E., Perkins, J.M.	Determination of Atmospheric Concentration of Sulfuryl Fluoride Following Fumigation of a Mill using ProFume – UK 2002	Agrisearch Uk Ltd, Melbourne, UK and Minnesota Valley Testing Laboratories, New Ulm, MN, USA	Y	N	N	Y (ii)	D	AF/6268/DE	July 2002

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
7.4.1.2	N	Kirk, A.D, Yaroch, A.M., Rick, D.L., McClymont, E.L., Krieger, S.M.	Sulfuryl Fluoride: An Acute Toxicity Study with the Daphnid, Daphnia magna Straus	Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA	Y	N	N	Y (ii)	D	011146	January 2002
7.4.1.1	N	Kirk, H.D., McClymont, E.L., McFaden, L.G., Rick, D.L., Yaroch, A.M.	Sulfuryl Fluoride: An Acute Toxicity Study with the Zebra-Fish, Brachydanio rerio, Hamilton-Buchanan	Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA	Y	N	Y	Y (ii)	D	011147R	March 2002
7.4.1.3	N	Kirk, H.D., Rick, D.L., Krieger, S.M., McFadden, L.G.	Sulfuryl Fluoride: Growth Inhibition Test with the Freshwater Green Alga, Selenastrum capricornutum Printz.	Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA	Y	N	N	Y (ii)	D	011145	January 2002

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
4.2d/01	N	Kissa, E	Determination of Inorganic Fluoride in Blood with a Fluoride Ion-Selective Electrode.	Clinical Chemistry, 33/2, 253-255 (1987)	N	Y	N	N	P	None	1987
3.2	N	Krieger, M.S.	Vapor Pressure of Sulfuryl Fluoride (SO2F2)	Regulatory Laboratories – Indianapolis Lab, Dow AgroSciences, Indianapolis, Indiana, USA	N	N	N	Y (ii)	D	GH-C 5319	November 2001
3.2.1	N	Krieger, M.S.	Henry's Law Constant for Sulfuryl Fluoride (SO2F2)	Regulatory Laboratories – Indianapolis Lab, Dow AgroSciences, Indianapolis, Indiana, USA	N	N	N	Y (ii)	D	GH-C 5306	November 2001
7.1.1.1.1 /02	N	Krieger, M.S.	Hydrolysis of Sulfuryl Fluoride (SO_2F_2)	Regulatory Laboratories, Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054	N	N	N	Y (ii)	D	GH-C 5346	November 2001

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
7.3.1 7.3.2	N	Krieger, M.S.	Atmospheric Fate and Global Warming Potential of Sulfuryl Fluoride (SO2F2)	Regulatory Laboratories, Dow AgroSciences, Indianapolis, Indiana, USA	N	N	N	Y (ii)	D	GH-C 5308	February 2002
4.3/09	Y	Lala M., Randolph, R.	Independent Laboratory Validation for Corn Oil and Raisins using Dow AgroSciences Method GRM 01.17 – Determination of Fluoride Anion in Corn, Wheat, Corn Oil and Flour.	Pyxant Labs Inc., Colorado Springs, Co. USA	Y	N	N	Y (ii)	D	020013 / 1404	March 2002
2.7 2.8	N	Langvardt, P.	Analytical Data Sheet 88-226, Vikane Inhalation	The Dow Chemical Company	N	N	N	Y (ii)	D	88-226	October 1988
2.7 2.8	N	Markham, D.A.	Chemical Purity, Analytical Report Number: 91-232. Vikane 18 month inhalation CD-1 mice and Vikane Reproduction	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	91-232	November 1991
2.7 2.8	N	Markham, D.A.	Chemical Purity of Vikane, K-016399-039 and K-016399-040, Analytical report code 90-137.	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	90-137	August 1990

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
2.7 2.8	N	Markham, D.A.	Chemical Purity, Analytical Report Number: 91-194.Vikane 18 month inhalation CD-1 mice	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	91-194	October 1991
2.7 2.8	N	Markham, D.A.	Chemical Purity, Analytical Report Number: 91-100. Vikane 18 month inhalation CD-1 mice.	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	91-100	May 1991
2.7 2.8	N	Markham, D.A.	Chemical Purity, Analytical Report Number: 93-54, Vikane 18 months mouse, 2-year rat and 1 year dog chronic inhalation studies	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	93-54	February 1993
2.7 2.8	N	Markham, D.A.	Chemical Purity, Analytical Report Number: 92-45, Vikane chronic/onco. Rat& mouse inhalation and Vikane 1-year chronic dogs	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	92-45	March 1992
2.7 2.8	N	Markham, D.A.	Chemical Purity, Analytical Report Number: 92-163. Vikane 18 month mouse, 2-year rat and 1-year dog chronic inhalation studies	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	92-163	July 1992

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.9/02	N	Mattson, J. L. Albee, R. R. Eisenbrandt, D. L. Nitschke, K. D.	Neurological Examination of Fischer 344 Rats exposed to Sulfuryl Fluoride (Vikane* Gas Fumigant) for 13 weeks	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-026	November 1986
6.9/04	N	Mattsson, J. L. Albee, R. R. Eisenbrandt, D. L.	Subchronic Neurotoxicity in Rats of the Structural Fumigant, Sulfuryl Fluoride	Health and Environmental Sciences, Dow Chemical , Midland. University of Arkansas for Medical Sciences. Little Rock, Arkansas	Y	Y	Y	N	P	Neurotoxicity & Teratology Vol. 10, No. 2, 1988, pp 127-133	March 1987
6.12.2	N	Maurissen,J.P., Burns,C.J.	Review of Publication: Neurobehavioral Evaluation of Soil and Structural Fumigators Using Methyl Bromide and Sulfuryl Fluoride. Anger,w.K., Moody,L., Burg,F., Brightwell,W.S., Taylor,B.J., Russo,J.M., Dickerson,N., Setzer,J.V., Johnson,B.L and Hicks,K. NeuroToxicol. 7: 137-156, 1986	The Dow Chemical Company, Midland, Michigan, USA	N	N	N	N	D	P11	July 2002

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
3.1.1/3.2	N	McDonald, R.A, Hildenbrand, D.L.	Some Physical Properties of Sulfuryl Fluoride	Dow Chemical Company	N	N	N	Y (ii)	D	SSR 226-624	June 1957
6.6.1/02	N	Mecchi, M.S.	Escherichia coli/Mammalian-Microsome Reverse Mutation Assay with a Confirmatory Assay with Sulfuryl Fluoride (gas)	Convance Laboratories Inc., Vienna, VA 22182, USA	Y	N	N	Y (ii)	D	011207, 23357-0-409OECD	April 2002
6.2	N	Mendrala, A.L., Markham, D.A., Clark, A.J., Krieger, S.M., Houtman, C.E., Rick, D.L.	Sulfuryl Fluoride: Pharmacokinetics and Metabolism in Fischer 344 rats	Toxicology & Environmental Research and Consulting The Dow Chemical Company, Midland, USA	Y	N	Y	Y (ii)	D	DECO HET K-016399-059 / 001166	May 2002
6.1.3/02	N	Miller, R. R. Calhoun, L. L. Keyes, D. G.	Sulfuryl Fluoride (Vikane* Fumigant) An LC50 Determination	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-013	August 1980
4.2b/01	N	Murphy, P.G., Contardi, J.S.	Sulfuryl Fluoride: Development and Validation of an Air Monitoring Method	DowElanco	N	N	N	Y (i)	D	HEH2.12-38-26(6)	July 1994

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.4.3/02	N	Nitschke, K. D. Beekman, M. J. Quast, J. F.	Sulfuryl Fluoride: 13-week Inhalation Toxicity Study in Beagle Dogs	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-041 K-016399-041A	February 1992
6.4.3/01	N	Nitschke, K. D. Dittenber, D. A. Eisenbrandt, D. L.	Sulfuryl Fluoride (Vikane* Gas Fumigant) 13-Week Inhalation Toxicity Study With Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-025R	November 1987
6.6.4	N	Nitschke, K. D. Gollapudi, B. B.	Response to U.S. EPA Comments on the Study entitled " Evaluation of Sulfuryl Fluoride in the Mouse Bone Marrow Micronucleus Test"	Dow Chemical Company, Midland	N	N	N	Y (ii)	D	TXT: K-016399-033	January 1991
6.1.3/03	N	Nitschke, K. D. Lomax, L. G.	Sulfuryl Fluoride: Acute LC50 Study with B6C3F1 Mice	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-028 K-016399-028A K-016399-028B	March 1989
6.10/04	N	Nitschke, K. D. Miller, R. R.	Sulfuryl Fluoride (Vikane* Gas Fumigant): Effects of Treatment With Calcium Gluconate or Anticonvulsants on Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET K-016399-024	April 1985

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.3.3/02	N	Nitschke, K. D. Quast, F. F.	Sulfuryl Fluoride: Two Week Inhalation toxicity Study in Beagle Dogs	Dow Chemical Company Midland	Y	N	Y	Y (ii)	D	K-016399-038	April 1991
6.1.3/04	N	Nitschke, K. D. Quast, J. F.	Sulfuryl Fluoride: Acute LC50 Study with CD-1 Mice	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-031; K-016399-031A; K-016399-031B	December 1990
6.4.3/04	N	Nitschke, K. D. Quast, J. F.	Sulfuryl Fluoride: Thirteen Week Inhalation Toxicity Study in CD-1 Mice	Dow Chemical Company, Midland	Y	N	Y	Y (ii)	D	K-016399-032	December 1993
6.4.3/05	N	Nitschke, K. D. Zimmer, M. A. Eisenbrandt, D. L.	Sulfuryl Fluoride (Vikane* Gas Fumigant): 13-Week Inhalation Toxicity Study With Rabbits	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-025B	November 1987
6.3.3/03	N	Nitschke, K.D., Quast, J.J.	Sulfuryl Fluoride: Two-Week Inhalation Toxicity Study in CD-1 Mice	Toxicology & Environment Research And Consulting, The Dow Chemical Company, Midland, Michigan, USA.	Y	N	Y	Y (ii)	D	DECO HET K-016399-029	February 2002

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
2.7 2.8	N	Putzig, C.L.	Analysis of sulfuryl fluoride by infrared spectroscopy for toxicology testing.	The Dow Chemical Company, Midland, Mi, USA	N	N	N	Y (ii)	D	ML-AL 92-050933	August 1992
6.4.3/03	N	Quast, J. F. Beekman, M. J. Nitschke, K. D.	Sulfuryl Fluoride: One Year Inhalation Toxicity Study In Beagle Dogs	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-044	October 1993
6.5/01	N	Quast, J. F. Bradley, G. J. Nitschke, K. D.	Sulfuryl Fluoride: 2-Year Inhalation Chronic Toxicity Oncogenicity Study in Fischer 344 Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET-K-016399-040	August 1993
6.5/02	N	Quast, J.F. Bradley, G. J. Nitschke, K. D.	Sulfuryl Fluoride: 18 Month Inhalation Oncogenicity Study in CD-1 Mice	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-039	August 1993
4.3/10	Y	Rick, D.L., Marty, G.T., Foster, D.R.	Determination of Fluoride Anion in Corn, Wheat, Corn Oil and Flour with a Fluoride Selective Electrode.	Dow Chemical Company, Midland, Mi, USA.	N	N	N	Y (ii)	D	GRM 01.17	April 2002
4.3/11	Y	Rick, D.L., Marty, G.T., Krieger, S.M., Byrne, S.L., Barnekow, D.E.	Magnitude of the Terminal Fluoride Ion Level in Cereal Grain Commodities Fumigated with Sulfuryl Fluoride	Dow AgroSciences, Indianapolis, USA	Y	N	Y	Y (i)	D	Study ID 011057	September 2001

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
2.7 2.8	N	Roll, H.	Vikane Product Release, Lot Number 141	The Dow Chemical Company	N	N	N	Y (ii)	D	HET-K-16399-13	March 1979
2.7 2.8	N	Russel, M.W., Nelson R.M	Certificate of Analysis for Test/Reference/Control Substances. Determination of purity and/or identity of the following test/references/control substances for use in a study.	Dow AgroSciences LLC, Indianapolis, Indiana 46268, USA	Y	N	N	Y (ii)	D	FA&PC Number 003109	May 2000
3.4.1, 3.4.2, 3.4.3, 3.4.4	N	Russell, M.W	Determination of the purity and identity of Sulfuryl Fluoride, TSN101693	Dow AgroSciences	Y	N	N	Y (ii)	D	NAFST244	May 2000
6.9/03	N	Spencer, P. J. Bradley, G. J. Quast, J. F.	Sulfuryl Fluoride: Chronic Neurotoxicity Study in Fischer 344 Rats – Final Report	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET K-016399-040B	March 1994
2.7 2.8	N	Stolz, W. L.	Series 62: Analysis and Certification of Product ingredients of VIKANE* Gas Fumigant	DowElanco Pittsburg	Y	N	N	Y (i)	D	FOR92080	March 1993
4.1/01	N	Stolz, W.L.,	Analytical Method for the Determination of Vikane* Gas Fumigant: Validation Report	Dow U.S.A. Western R& D Pittsburg	N	N	N	Y (i)	D	FOR92080.01	March 1993

98/8 Section Number (IIIA)	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
4.1/02	N	Stolz, W.L., Fields S.M.	Analytical Method for the Determination of Selected Impurities in Vikane* Gas Fumigant: Validation Report	Dow U.S.A. Western R& D Pittsburg	N	N	N	Y (i)	D	FOR92080.02	March 1993
6.1.3/05	N	Vernot, E.H., MacEwen J.D., Haun, C.C.,, Kinkead, R.R.	Acute Toxicity and Skin Corrosion Data for Some Organic and Inorganic Compounds and Aqueous Solutions (University of California, Irvine, Toxic Hazards Research Unit, Overlook Branch, Dayton, Oh8io 45431)	Toxicology and Applied Pharmacology 42, 417-423 (1977)	N	Y	N	Y (ii)	D	None	January 1977

List of studies for the product related endpoints (sorted by author)

98/8 Section Number III-B	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
3.8	N	Anon	Sulfuryl Fluoride, Temperature Dependent Properties, PPDS System DataBank	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	PPDS 2790	July 2002
5.10.2/48	Y	Anon.	Study of the efficacy of sulfuryl fluoride, $S0_2F_2$, to protocol CEB 213.	Ministry of Agriculture and Fisheries, France.	Y	N	N	Y (ii)	D	None	2001
9.	N	Anon	Package Material Specification, Valve – Vikane Cylinders	The Dow Chemical Company and Superior Valve Company	N	N	N	N	D	00014268	January 1995
6.1.1	N	Anon	The Acute Oral Toxicity to Vikane Administration of Single Doses to Male Rats, Female Rats and Guinea Pigs	Dow Chemical Company, Midland	N	N	Y	Y (ii)	D	None	October 1959
6.1.3/01	N	Anon	The Acute Vapor Toxicity Of Vikane As determined on Male and Female Rats	Dow Chemical Company, Midland	N	N	Y	Y (ii)	D	None	October 1959

98/8 Section Number III-B	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.6/02F1	N	Barnekow, D.E, Byrne, S.L. Foster, D.R.	Sulfuryl Fluoride Exposure Potential to Workers Involved in the Fumigation and Aeration of Mills Using ProFume – North America	Global Environmental Chemistry Laboratory, Dow AgroSciences , Indianapolis, Indiana, USA	Y	N	N	Y (ii)	D	010052	March 2002
6.6/02G1 6.6/02G2	N	Barnekow, D.E., Byrne, S.L., Foster, D.R.	Determination of Atmospheric Concentrations of Sulfuryl Fluoride Following Fumigation of Mills Using ProFume – North America 2000.	Reg. Laboratories, Indianapolis, Dow AgroSciences, Indiana, USA	Y	N	N	Y (ii)	D	000329	February 2002
6.6/02F2 6.6/02F3	N	Barnekow, D.E., Byrne, S.L., Foster, D.R., Robb, C.K	Determination of Atmospheric Concentrations of Sulfuryl Fluoride Following Fumigation of Mills Using ProFume- North America 2001	Paragon Research Services, Fresno, CA, USA and MVTL Laboratories, New Ulm, Min, USA and Reg. Laboratories, Dow AgroSciences, Indianapolis, USA	Y	N	N	Y (ii)	D	010039	December 2001

98/8 Section Number III-B	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.6/02H1 6.6/02H2	N	Barnekow, D.W., Byrne, S.L., Foster, D.R.	Determination of Exposure Potential to Workers and Atmospheric Concentrations of Sulfuryl Fluoride During and Following Fumigation of Mills Using ProFume – North America 2002	Paragon Research Services, Fresno, CA, USA and MVTL Laboratories, New Ulm, MN, USA and Reg. Laboratories-Indianapolis Lab, Dow AgroSciences LLC, Indianapolis, IN, USA	Y	N	N	Y (ii)	D	020039	June2002
5.10.2/45	Y	Bell, C.H.,	The concentration-time relationship for eggs of *Ephestia kuehniella* and *Tribolium castaneum* at 25 and 30^{o}C in fumigation tests with sulfuryl fluoride.	Central Science Laboratory, York, UK.	Y	N	N	Y (ii)	D	None	2001
5.10.2/47	Y	Bell, C.H., Cardwell, S.K	Toxicity of sulphuryl fluoride to eggs and adults of five food processing pests, *Dermestes maculatus, Ephestia cautella, Lasioderma serricorne, Oryzaephilus surinamensis and Stegobium paniceum* at 20, 25 and 30^{o}C.	Central Science Laboratory, York, UK.	Y	N	N	Y (ii)	D	None	2004

98/8 Section Number III-B	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
5.10.2/46	Y	Bell, C.H., Cardwell, S.K.	ProFume fumigation tests on post embryonic stages of *Ephestia kuehniella*, *Oryzaephilus surinamensis* and *Tribolium castaneum* at 20, 25 and 30^{o}C including for *T. castaneum* an examination of the concentration-time relationship at 25^{o}C.	Central Science Laboratory, York, UK.	Y	N	N	Y (ii)	D	None	2001
5.10.2/42	Y	Bell, C.H., Savvidou, N.	A report on a study of the toxicity of Vikane (sulfuryl fluoride) to age groups of eggs of the Mediterranean flour moth (*Ephestia kuehniella*).	Central Science Laboratory, York, UK.	Y	N	N	Y (ii)	D	None	1998
5.10.2/44	Y	Bell, C.H., Savvidou, N.	Report on the toxicity of Vikane to eggs of *Ephestia kuehniella*, *Tribolium castaneum* and *Trogoderma variabile* at 20^{o}C including tests on the concentration time relationship.	Central Science Laboratory, York, UK.	Y	N	N	Y (ii)	D	None	1999
5.10.2/43	Y	Bell, C.H., Savvidou, N., Wonter-Smith, T. J.	The toxicity of sulfuryl fluoride to eggs of insect pests of flour mills.	Central Science Laboratory, York, UK.	Y	N	N	Y (ii)	D	None	1998

98/8 Section Number III-B	Study sub-mitted for first time for PT18 (Y/N)	Author	Title	Laboratory	GLP/GEP Study Y/N	Published Y/N	Vertebrate Study Y/N	Data Protection Claimed Y/N	Data Owner	Report No. / Study ID	Report Date
6.6/02D1 6.6/02D2 6.6/02D3	N	Blaschke, U.	Sulfuryl Fluoride, Determination of Atmospheric Concentrations of Sulfuryl Fluoride and Occupational Exposure of Fumigators during the structural Fumigation of a Mill using ProFume Germany 2002	Huntingdon Life Sciences, Ltd, Huntingdon, UK	Y	N	N	Y (ii)	D	DOS 299/023404	July 2002
6.1.2	N	Bradley, G. J Landry, T. D. Battjes, J. E. Quast, J. F.	Sulfuryl Fluoride: Four-Hour Dermal Vapor Exposure in Fischer 344 Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-036 K-16399-36 K-016399-036A K-0L6399-036B	November 1990
3.1.2	N	Comb, A.L.	Determination of Physico-Chemical Properties for Sulfuryl Fluoride	Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, PE28 4HS, England	Y	N	N	Y (ii)	D	NAFST430	June 2001

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3.10.1	N	Comb, A.L.	Determination of Physico-Chemical Properties for Sulfuryl Fluoride	Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, PE28 4HS, England	Y	N	N	Y (ii)	D	NAFST430	June 2001
9.	N	Friese, D.D.	Corrosion Rates of Steel Cylinders in Vikane (Fumigant) Service	Dow Chemical, Pittsburg, Ca, USA	N	N	N	Y (ii)	D	DECO GB 3928 / CRI 2002000177	November 2001
2.2	N	Ghaoui, L.H.	Group A: Product Identity and Composition, Description of Materials used to Product the Product, Description of the Production Process, Discussion of Formation of Impurities, Certified Limits, Preliminary Analysis, and Enforcement Analytical Methods for Sulfuryl Fluoride Technical	Formulation Science and Technology, Dow AgroSciences, Indianapolis	N	N	N	Y (ii)	D	NAFST361	January 2001
6.6/02B1 6.6/02B2 6.6/02B3	N	Jones, G.E., Perkins, J.M.	Determination of Atmospheric Concentration of Sulfuryl Fluoride Following Fumigation of a Mill using ProFume – UK 2002	Agrisearch Uk Ltd, Melbourne, UK and Minnesota Valley Testing Laboratories, New Ulm, MN, USA	Y	N	N	Y (ii)	D	AF/6268/DE	July 2002

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7.2	N	Kirk, A.D, Yaroch, A.M., Rick, D.L., McClymont, E.L., Krieger, S.M.	Sulfuryl Fluoride: An Acute Toxicity Study with the Daphnid, Daphnia magna Straus	Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA	Y	N	N	Y (ii)	D	011146	January 2002
7.2	N	Kirk, H.D., McClymont, E.L., McFaden, L.G., Rick, D.L., Yaroch, A.M.	Sulfuryl Fluoride: An Acute Toxicity Study with the Zebra-Fish, Brachydanio rerio, Hamilton-Buchanan	Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA	Y	N	Y	Y (ii)	D	011147R	March 2002
7.2	N	Kirk, H.D., Rick, D.L., Krieger, S.M., McFadden, L.G.	Sulfuryl Fluoride: Growth Inhibition Test with the Freshwater Green Alga, Selenastrum capricornutum Printz.	Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA	Y	N	N	Y (ii)	D	011145	January 2002

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7.5	N	Krieger, M.S.	Environmental Fugacity Modeling of Sulfuryl Fluoride (SO2F2)	Regulatory Laboratories, Dow AgroSciences, Indianapolis, Indiana, USA	N	N	N	Y (ii)	D	GH-C 5307	November 2001
6.1.3/02	N	Miller, R. R. Calhoun, L. L. Keyes, D. G.	Sulfuryl Fluoride (Vikane* Fumigant) An LC50 Determination	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-013	August 1980
6.1.3/03	N	Nitschke, K. D. Lomax, L. G.	Sulfuryl Fluoride: Acute LC50 Study with B6C3F1 Mice	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-028 K-016399-028A K-016399-028B	March 1989
6.1.3/04	N	Nitschke, K. D. Quast, J. F.	Sulfuryl Fluoride: Acute LC50 Study with CD-1 Mice	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-031; K-016399-031A; K-016399-031B	December 1990

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6.6/02A1 6.6/02A2	N	Perkins, J.M.	Determination of Atmospheric Concentrations of Sulfuryl Fluoride Following Fumigation of a Mill using ProFume – UK 2000	Dow AgroSciences, Letcombe Laboratories, Wantage, UK and Minnesota Valley Testing Laboratories (MVTL) New Ulm, MN, USA	Y	N	N	Y (ii)	D	000377	July 2002
6.6/02C1 6.6/02C2	N	Perkins, J.M.	Determination of Atmospheric Concentrations of Sulfuryl Fluoride following Fumigation of a Mill using ProFume – Germany 2000	Dow AgroSciences, Letcombe Laboratory, Wantage, UK and Minnesota Valley Testing Laboratories, New Ulm, MN, USA	Y	N	N	Y (ii)	D	000303	July 2002

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6.6/02E1 6.6/02E2	N	Perkins, J.M.	Determination of Atmospheric Concentrations of Sulfuryl Fluoride following Fumigation of a Mill using ProFume – Italy 2001	Dow AgroSciences, Letcombe Laboratory, Wantage, UK and Minnesota Valley Testing Laboratories (MVTL), New Ulm , MN, USA	Y	N	N	Y (ii)	D	010073	July 2002
5.11	N	Prabhakaran, S.K. and Ray, S.	ProFume Resistance Risk Analysis (Sequential Quantitative Resistance Model)	Dow AgroSciences, Mooresville, USA	N	N	N	Y (ii)	D	None	December 2002
3.7	N	Russell, M.W.	Stability of Sulfuryl Fluoride	Dow AgroSciences, Indianapolis, USA	Y	N	N	Y (ii)	D	NAFST383	August 2001
9.	N	Ryan, B.	Vikane Cylinder Hydrotester Operating Procedure	Dow AgroSciences, Pittsburgh, Ca, USA	N	N	N	N	D	None	
4.1/01	N	Stolz, W.L.	Analytical Method for the Determination of Vikane* Gas Fumigant: Validation Report	Dow U.S.A. Western R& D Pittsburg	N	N	N	Y (i)	D	FOR92080.01	March 1993

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98/8 Section Number III-B	**Study sub-mitted for first time for PT18 (Y/N)**	**Author**	**Title**	**Laboratory**						**Report No. / Study ID**	**Report Date**
5.10.2/50	Y	Thoms, E., Hartsell, P., Keeler, L., Schneider, B.	Concentration-time relationship for fumigant efficacy of sulfuryl fluoride against the Indian meal moth *Plodia interpunctella* eggs at 25°C and 30°C.	Dow AgroSciences, Indianapolis, USA.	Y	N	N	Y (ii)	D	None	2001
6.1.3/05	N	Vernot, E.H., MacEwen J.D., Haun, C.C.,, Kinkead, R.R.	Acute Toxicity and Skin Corrosion Data for Some Organic and Inorganic Compounds and Aqueous Solutions (University of California, Irvine, Toxic Hazards Research Unit, Overlook Branch, Dayton, Ohio 45431)	Toxicology and Applied Pharmacology 42, 417-423 (1977)	N	Y	N	Y (ii)	D	None	January 1977
5.10.2/49	Y	Williams, R.E., Thoms, E.	Sulfuryl fluoride laboratory efficacy summary of stored product insects from the Dried Fruit and Nut Association of California, 1996-1999.	Dow AgroSciences, Indianapolis, USA	Y	N	N	Y (ii)	D	None	2000

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