Competent Authority Report

Work Programme for Review of Active Substances in Biocidal Products
Pursuant to Council Directive 98/8/EC

SULFURYL FLUORIDE (PT18)

DOCUMENT III-A1-A3

Active Substance
Applicant, Identity and Physical and Chemical Properties

Rapporteur Member State: Sweden

Draft June 2007
Final April 2008

KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

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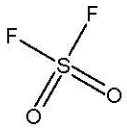
Section A1 Applicant

Annex Points IIA, I.1.1 to 1.2

Subsection			Official use only
1.1	Applicant	[redacted]	
1.2	Manufacturer of Active Substance (if different)	[redacted]	X1
1.3	Manufacturer of Product(s) (if different)	Same as above	
	1) Product 1		

Section A2 Identity of Active Substance

Annex Points IIA, II.2.1 to 2.9

Subsection						Official use only
2.1	**Common name (IIA2.1)**	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.)				
2.2	**Chemical name (IIA2.2)**	Sulfuryl fluoride (CA) Sulfuryl difluoride (IUPAC)				
2.3	**Manufacturer's development code number(s) (IIA2.3)**	No development numbers have been used for sulfuryl fluoride				
2.4	**CAS No and EC numbers (IIA2.4)**					
2.4.1	**CAS-No**	2699-79-8				
	Isomer 1	Not applicable Sulfuryl fluoride is an inorganic substance and does therefore not contain any stereo isomers.				
2.4.2	**EC-No**	220-281-5 (EINECS)				
	Isomer 1	Not applicable Sulfuryl fluoride is an inorganic substance and does therefore not contain any stereo isomers.				
2.4.3	**Other**	-/-				X2
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**					
2.5.1	**Molecular formula**	SO_2F_2				
2.5.2	**Structural formula**					
2.5.3	**Molecular mass**	102.1				
2.6	**Method of manufacture of the active substance (IIA2.6)**	Confidential information, see Annex Confidential Data and Information				
2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	g/kg	g/l	% w/w Min 99.4 Aim 99.8 Max 100	% v/v	

Section A2 Identity of Active Substance

Annex Points IIA, II.2.1 to 2.9

Subsection			Official use only
2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	Confidential information, see Annex Confidential Data and Information	
2.8.1	**Isomeric composition**	Not applicable Sulfuryl fluoride is an inorganic substance and does therefore not contain any stereo isomers.	
2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**	Chemical	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2007
Materials and methods	The applicant's version is adopted.
Conclusion	The applicant's version is adopted.
Reliability	**Subsection 2.7** Reliability indicator 1: Study conducted in compliance with agreed protocols, with no or minor deviations from standard test guidelines and/or minor methodological deficiencies, which do not affect the quality of relevant results **All other subsections under section A1 and section A2** Reliability indicator 0: Not applicable since no studies were performed for these subsections.
Acceptability	All subsections under section A1 and section A2 have been addressed and the information provided is sufficient and acceptable.
Remarks	**1.2 Manufacturer of Active Substance** X1: In May 2007 the old plant was replaced by a new modern plant with higher capacities at the same location. The new plant utilises the same manufacturing process as the old one (see Annex Confidential Data and Information) and was introduced in order to satisfy the quantities required by the market. The new plant will be fully operational in August 2007. The applicant has stated that batch data for the new plant will be available in February 2008. **2.4.3 Other numbers for the active substance** X2: Sulfuryl fluoride is assigned CIPAC No.: 757.

Section A2.10 **Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC**

Annex Point IIA, II.2.10

Subsection		Official use only
2.10.1 Human exposure towards active substance		
2.10.1.1 Production	Of the product ProFume* (TM for PT18 application)	
i) Description of process	The biocidal product is manufactured in the USA. For products manufactured outside the European Union, no details on production need to be included.	
ii) Workplace description	See above	
iii) Inhalation exposure	See above	
iv) Dermal exposure	See above	
2.10.1.2 Intended use(s)	MG03: Pest Control PT18: Insecticides Fumigant for pest control in emptied food processing facilities. ProFume is used e.g. in the following establishment types: Cereal processors (eg breakfast cereal products) Flour based products (eg biscuits, cakes, bakeries) Chocolate confectionary Dried fruit and nut packers and processors Pet food manufactureres ProFume is used as a fumigant for the control of stored product insect pests (SPIs) in emptied food processing facilities and emptied storage facilities. Prior to fumigation all machinery is run out to complete emptiness and then dry cleaned. All storage areas and silos are normally emptied. All stored finished products are removed. No food materials are left in areas to be fumigated. Stored product insects present a serious problem for the Food Industry causing direct physical damage and contamination of food destined for animal or human consumption. The economic loss in manufacturing, storage and shipment can be profound. Industry standards demanded by national government legislation and EU directives on food quality and hygiene are high and are challenging to meet. Dow AgroSciences has a strict product stewardship policy to augment the training and certification required by local government authorities. In common with other fumigants sulfuryl fluoride has unique hazards that require full understanding and correct execution of application and safety measures to ensure effective insect control with minimal risk to operators and the	

* Trademark of Dow AgroSciences

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Annex Point IIA, II.2.10

	public.
1. Professional Users	Dow AgroSciences is committed to a comprehensive product stewardship programme which minimises potential risk to operators and bystanders. These programmes will meet or exceed Member States' existing guidance and legislation for the conduct of fumigations. Only those individuals, who attend, pass and adhere to our strict health and safety policies will be allowed to use ProFume; such training is mandatory and has to be reviewed on an annual basis. Only those professional fumigators who have been certified under local country regulations AND who have been approved by Dow AgroSciences.
i) Description of application process	PT18 The same method of application and system used described for PT8 for structural fumigation is used for the 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) and machinery.
ii) Workplace description	Structural fumigation (PT18) Structural fumigation (emptied food processing facilities) is a periodic/seasonal activity similar to the mill fumigation scenario. Temperature is an important factor to consider in fumigation. The higher the temperatures the less gas is needed, the shorter the fumigation time can be and the better the efficacy. Therefore structural fumigation is mainly done during the warmer months of the year. Potential exposure could happen to bystanders and operators. Professional fumigator exposure would be essentially limited to structural fumigations. Data from 'worst-case' structural fumigations trials show that operator exposure would most often be less than 1 ppm over an 8-hr working day, but could occasionally exceed 3 ppm. Mandatory use of SCBA (during gas introduction and aeration) would reduce these values to even lower levels during commercial use of sulfuryl fluoride. Bystanders can be incidental or residential. Exposure of residential or incidental bystanders around a structural fumigation are be limited to a single, isolated occasion over a period of a year or more. Therefore incidental (passing by) bystander exposure represents a negligible risk scenario for which risk characterization and management are considered unnecessary. The worse-case for bystanders is the residential situation. *a) Introduction of the fumigant* Structure is well sealed to achieve virtual gas tightness. Fumigation lines, as well as monitoring lines, are laid into the building. The operation to introduce the gas is managed from outside of the structure. The operator will wear SCBA during gas introduction.

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Annex Point IIA, II.2.10

	b) Surveillance of fumigant concentration during fumigation Gas concentrations inside the structure are measured via monitoring lines. The monitoring lines are attached to a calibrated Fumiscope located outside the fumigated structure. Surveillance of the gas concentration around the fumigated structures is done by using a calibrated hand-held Interscan. When external air concentrations are above the Upper Limit Ceiling Value of 3 ppm, operators have to vacate the area or immediately don SCBA. An exclusion zone of 10 metres will ensure that residential bystander exposure does not exceed the 24-hour TWA limit of 3 ppm.	X1
	c) Aeration of structure Aeration occurs via the highest possible point of the structure (e.g., through the bell tower in the case of a church). Fumigators will start the fumigation process either from outside (where possible) or from inside, wearing SCBA. At the end of the aeration period, a fumigator wearing SCBA enters the fumigated premises to measure the gas concentrations. Only after all gas concentrations are measured and confirmed to be below the AOEC for the bystander and worker of 3 ppm is SCBA removed and a building officially signed-over to the owner. An exclusion zone of 10 metres will ensure that residential bystander exposure does not exceed the 24-hour TWA limit of 3 ppm.	
	d) Duration and frequency of the operation and the recommended Personal Protection Equipment Variable as described in the Human Exposure Document. Fumigators will wear SCBA (Self contained breathing apparatus), as a mandatory requirement, when introducing the gas, re-entering a structure and if air concentrations exceed the Upper Limit Ceiling Value of 3 ppm. Rubber boots and gloves should not be worn, because of danger of freeze burns in case the liquid gas under pressure gets trapped in the rubber boots or gloves.	X1
iii) Inhalation exposure	Operator exposure refers to potential exposure of the person or persons involved in tasks relating to fumigation and aeration of the structure. A summary of air concentrations in 10 fumigation trials across Europe and the USA is tabulated below.	

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Sulfuryl Fluoride - Summary of potential fumigator exposure

91/414 Annex III Point	Trial (Reference No)	Operator	Mean 8 h TWA multidirectional air concentrations (ppm)	Potential exposure as % of AOEC of 1 (i.e., with no reduction for SCBA)
7.2.1.2/01	UK 2000 (K29)	Fumigator	0.04	4
7.2.1.2/02	UK	Fumigator	0.05	5
	2002 (K30)	Aerator	0.19	19
7.2.1.2/03	Germany	Fumigator	0.12	12
	2000 (K31)	Aerator	0.52	52
7.2.1.2/04	Germany	Fumigator	0.93	93
	2002 (K32)	Aerator	0.82	82
7.2.1.2/05	Italy 2001 (K33)	Fumigator	0.56	56
7.2.1.2/06	SOTW, US	Fumigator	2.06	206
		Aerator	0.19	19
	SCFM, US	Fumigator	3.35	335
		Aerator	0.855	85
	ARI, TX,	Fumigator	1.06	106
7.2.1.2/07	SOTW, US 2000	Fumigator	1.97	197
	(K27)	Aerator	1.48	148
7.2.1.2/08	SOTW, US,	Fumigator	0.97 (2.19)	97 (219*)
	(K34)	Aerator	0.44	44
Mean		Fumigator	1.11	111
		Aerator	0.64	64
		Overall	0.92	92

(*) For duplicate samples obtained from two workers, one of 4 samples was ca. 10X higher than the other three samples collected. Therefore, this outlier was excluded from calculation of the mean values as it was considered not to be a true representative value.

A toxicologically based AOEC of 1ppm has been set. It is derived from the 90-day subchronic study in mice with a NOAEL of 30ppm using a 10 x 10 safety factor. The AOEC means that this is the level that a worker could be exposed to constantly for a full working day over a longer period of time. The AOEC of 1 ppm is an 8hr- time weighted average. The 'enforcement value - ceiling limit value' (terminology to be determined) for the fumigators is 3ppm. By using 3ppm as a ceiling value for the fumigator to retreat and put on SCBA it is ensured that the time-weighted average AOEC of 1ppm is not exceeded. Using this approach ensures gas concentration can be realizably monitored in real time and one figure (3ppm) is used as single-value-for all (for the operator and the bystander) to eliminate confusion. X1

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	In conclusion: potential operator exposure resulting from the use of sulfuryl fluoride in structural fumigations has been investigated in 10 individual trials. TWA air concentrations above the proposed AOEC of 1 ppm occurred in 3 US trials, none of the EU trials showed exceedenses. Additional use of respiratory protection (SCBA) in accordance with the ProFume recommendations (i.e., when working directly with cylinders during the introduction of gas and when working in or entering areas where the concentration exceeds the Upper Limit Ceiling Value of 3 ppm) would substantially reduced exposure. These data show that use of ProFume would be without any adverse effects on health of fumigators. The SCBA is effectively 100 % efficient and no exposure results from wearing SCBA in a house. The fumigator is not in a rush to put on SCBA, since he first measures, in case of SF concentration, he will then back up and put on properly the SCBA (there is a standard procedure to put on SCBA - it is tested, checked for tightness and functionality everytime it is used), only then he will proceed into the risk zone. Bystanders (could be passers-by, or residents in the vicinity of the structure) are not exposed to gas concentrations above the AOEC. The fumigator has to set the risk zone to exclude such possibility. In case a neighbouring house is too close (and the fumigator has to measure gas concentration), this house would belong to the risk zone and residents would have to leave, the same is true for roads and pathways.	X1
iv) Dermal exposure	Exposure to sulfuryl fluoride is via inhalation only. Results of the acute percutaneous toxicity study (4-hour dermal vapour exposure in fisher 344 rats) (**Ref. 91/414 IIIA 7.1.2/01, B07**)) indicate no acute toxicological hazard on exposure to sulfuryl fluoride via the skin. Sulfuryl fluoride is a gas packed under pressure in cylinders. Upon accidental contact with the liquid gas under pressure, the gas will evaporate. Operators are advised not to wear protective rubber gloves or boots. If sulfuryl fluoride is trapped in gloves or boots the gas (boiling point -54°C, **Ref. 91/414 IIA, 2.1.2/01**) will cause freeze burns.	
2. Non-professional Users including the general public	The product is excluded from being used by non-professionals or the general public.	
(i) via inhalational contact	Bystanders 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. Data show that even if a person stayed within 5 metres of a structure for 24 hours the exposure would not exceed an AOEC of 3 ppm (Ref. 91/414 MIII, Section 3, Point 7.2.2). In reality, this situation represents a negligible risk scenario for which risk characterization and management are considered unnecessary. The worse-case for bystanders is represented by the residential situation. In this case, unidirectional 24-hour TWA air	X2

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concentrations are relevant and a summary of air concentrations around 11 mills across Europe and the USA is tabulated below.

Sulfuryl Fluoride - Summary of Bystander Exposure – Uni-Directional 24 h TWA

European Mills	**Maximum 24-hour *Uni-Directional* Time Weighted Average (ppm)**				
91/414 Annex III Point (Ref. No.)	7.2.2.2/01 (K29)	7.2.2.2/02 ((K30)	7.2.2.2/03 (K31)	7.2.2.2/04 (K32)	7.2.2.2/05 (K33)
Nominal Distance	**UK 2000**	**UK 2002**	**Germany 2000**	**Germany 2002**	**Italy 2001**
5m	1.77	0.18	0.3	1.54	2.73
10m	1.24	0.19	0.37	1.5	1.32
25m	0.79	0.15	0.27	0.85	0.78
50m	0.54	0.09	0.17	0.34	0.51
75m	0.07	0.01	0.17	0.2	0.31

US Mills	**Maximum 24-hour *Uni-Directional* Time Weighted Average (ppm)**					
Annex III Point:	7.2.2.2/06 (K25)	7.2.2.2/06 (K25)	7.2.2.2/06 (K25)	7.2.2.2/07 (K27)	7.2.2.2/07 (K27)	7.2.2.2/08 (K34)
Nominal Distance	**SOTW**	**SCFM**	**ARI, TX**	**SOTW**	**ARI, CA**	**US 2002**
5m	2.14	0.9	0.33	7.02*	3.94	4.76**
10m	1.15	0.71	0.19	4.47*	3.09	2.59
25m	0.57	0.44	0.16	0.94	1.56	2.32
50m	1.09	0.28	0.15	0.44	0.99	1.08
75m	0.63	0.22	0.12	0.4	0.52	1.07
>75m	0.46	0.12	-	0.09	0.29	0.45

*These values due to leakage from a connected unsealed office area which was unintentionally fumigated. The distance from the point source (i.e. the office) was shorter than that recorded as nominal.
** These values due to leakage from fumigation procedure which would not be used in a commercial fumigation.

In conclusion: The potential bystander exposure resulting from the use of sulfuryl fluoride gas in 11 individual fumigation trials indicates that an initial 10 metre exclusion zone would be reasonable and pragmatic. In accordance with guidance from government bodies, such as UK HSE, and fumigation associations, such as British Pest Control Association, this exclusion zone should be monitored and adjusted if required, to ensure that exposures remain below acceptable levels. X3

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(ii) via skin contact	Exposure to sulfuryl fluoride is via inhalation only.
(iii) via drinking water	Sulfuryl fluoride will not directly impact surface water bodies because of its physical properties and use patterns. Spray drift and runoff and other typical routes of entry of biocides into aquatic ecosystems are not relevant for a permanent gas such as sulfuryl fluoride with no terrestrial or aquatic use patterns. As negligible amounts of sulfuryl fluoride are expected to be present in soil (PECsoil approximately 6 x 10^{-14} mg/kg) as a result of the physical properties and use patterns, and as confirmed by the fugacity modelling (see 91/414, M-III, **Point 9.1.3**), the potential for sulfuryl fluoride to reach groundwater at concentrations >0.1 µg/L is negligible. There are no relevant metabolites, degradation and reaction products. The results of the fugacity modelling can be found in Doc III, B7.5.
(iv) via food	Not applicable Prior to fumigation of emptied food processing facilities all machinery is run out to complete emptiness and then dry cleaned. All storage areas and silos are normally emptied. All stored finished products are removed. No food materials are left in areas to be fumigated.
(v) indirect via environment	Sulfuryl fluoride is a gas under all environmental conditions (boiling point -54°C, see **Ref. 91/414 IIA 2.1.2/01, A15**) and has an extremely high vapour pressure (1,611,467 Pa at 20°C, see **Ref. 91/414 IIA 2.3.1/01, A20**). These properties, combined with the relatively unique use pattern of sulfuryl fluoride as a structural and commodity fumigant, result in negligible exposure and risk to terrestrial and aquatic ecosystems. As described in the Human Exposure Document indirect exposure at fumigation may occur to the by-stander via inhalation. This scenario has been described in Section 2 (i) above. Studies conducted in mills (**91/414, M-III, pt. 7.2**), which represent a worst-case scenario in terms of building size and gas volume used, showed that air concentrations 10 m or more from the fumigated structure would not exceed the proposed AOEC of 3 ppm. An exclusion zone of 10 m around a fumigated structure (e.g., emptied food processing facility) will ensure no exposure to a residential bystander above the AOEC. See DOC III, B6.6/02 (Annex point IIB, VI.6.6), bystander exposure.
2.10.2 Environmental exposure towards active substance	Environmental exposure to SO_2F_2 occurs only after use of the product for fumigation and release of the product to the atmosphere at the completion of the fumigation event. The frequency of exposure will be determined by the specific number of fumigation events conducted in any given time period. Because the exact number of potential environmental exposures over short time periods will be variable and unpredictable, environmental exposures have been estimated using two limiting scenarios. These two scenarios represent either a single fumigation event (releasing 3840

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kg of SO_2F_2 to the atmosphere) or the sum of all fumigation events expected to occur globally in a single calendar year (releasing 1.86 x 10^6 kg of SO_2F_2 to the atmosphere - This figure represents the average annual, global production/emission of sulfuryl fluoride from 1992-2000. *Please note that this figure is highly confidential and may not be disclosed outside the government regulatory authorities.*

In both cases these release scenarios were modelled assuming the entire mass of SO_2F_2 was released at the same time.

The atmosphere is the environmental compartment that is directly exposed during release of SO_2F_2 from a fumigated structure. Fugacity modeling demonstrates that SO_2F_2 will not partition to soil or sediment from the atmosphere. While ocean surface waters are a sink for SO_2F_2 because of rapid chemical hydrolysis, fugacity modeling also demonstrates that because of this rapid degradation ocean surface waters will serve as sink but not a reservoir for SO_2F_2, and therefore the predicted environmental concentrations in surface water are negligible. These results are consistent with the physical properties of SO_2F_2. The duration of the exposure can be considered to be essentially negligible to soil, sediment, and water since there is no measurable exposure, while the duration of the exposure in the air compartment will be long-term based on the estimated upper limit of the atmospheric lifetime of <4.5 years (the estimated atmospheric half-life on the other hand is <3.2 years). For estimates of atmospheric lifetime and half-life see Doc III-A7.3.1 (Ref. K28). X4

2.10.2.1 Production The biocidal product is manufactured in the USA. According to the TNsG Data Requirements, Ch.2, 2.10 and 6.6, for products manufactured outside the European Union, no details on production need to be included.

(i) Releases into water: The only waste from this process is a small alkaline scrubber effluent which results from absorption of the various plant gasses during equipment maintenance and emergency venting.

(ii) Releases into air: Air emissions are covered under an air permit in the United States.

(iii) Waste disposal: Scrubber effluent is treated at an approved waste disposal facility in the United States. Other minor waste materials are incinerated in an approved and licensed facility.

2.10.2.2 Intended use(s) The percentage distributions for affected compartments are based on the global fugacity modelling, which yields corresponding PECs based on the total annual production volume (1.86 x 10^6 kg), while the PECs resulting from a single application are also presented. The 3840 kg input is not from a regional scenario, it is from a single use scenario. X5

Affected compartment(s): Distribution calculated using a Level II fugacity (Mackay) model. **(Ref. 91/414 Doc M-III, section 5, IIIA 9.0.1/01, K24)**

Distribution calculated using a Level II fugacity (Mackay) model can be found in Doc III-B7.5 (Ref. K24).

PECwater: 0.0068% of sulfuryl fluoride released will partition into water.

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	PECwater = 5.66×10^{-9} µg/L (based on total annual global production and emissions).
PECsediment	0.0000% of sulfuryl fluoride released will partition into the sediment. PECsediment = 1.28×10^{-13} mg/kg (based on total annual global production and emissions). When the first Level I fugacity modelling was made (see Doc III-B7) using the default, regional-scale environmental properties, it was shown that the sediment (as well as fish, suspended sediment, aerosols and soil) contained a negligible fraction of sulfuryl fluoride at equilibrium ($\leq 10^{-6}$%). When the global environment was simulated the volume of the sediment compartment (and fish and suspended solids) was set to zero and therefore the percentage output result will of course be 0%.
PECair	99.9932% of sulfuryl fluoride released will partition into the air. PECair = 0.088 ppt (volume/volume) (ppt = parts per trillion, 10^{12}) (based on total annual global production and emissions), or 0.367 ng/m^3.
PECsoil	1.37×10^{-7}% of sulfuryl fluoride released will partition into the soil. PECsoil = 6.41×10^{-14} mg/kg (based on total annual global production and emissions).
Predicted concentration in the affected compartment(s)	PECs based on a realistic maximum application to a building volume of 30 000 m^3 at a dose rate of 128 g/m^3 (total = 3840 kg). PECs estimated by multiplying the PECs estimated for annual production and use values by the maximum realistic application in a single application (3840 kg / 1.86×10^6 kg annually). (The building volume was assumed the worst case in terms of size – a very large building (e.g. mill) to be fumigated). Here, PEC values for the different compartments on a global scale have been calculated with a single use (amount) input. It should be pointed out though, that since sulfuryl fluoride is a gas under all environmental conditions the calculations of PEClocal, PECregional or PECsingle_use will be highly imaginary and of very little value for the understanding of the distribution and the levels to expect in the environment. Sulfuryl fluoride emitted to the atmospheric environment (or to any environmental compartment) will not only be distributed within the boundaries of the local or regional scales but will be distributed over a much larger area (or rather volume). But, in theory any theoretical spatial scenario can be modelled if the amount of sulfuryl fluoride emitted is known together with a knowledge of the compartmental volumes of interest. The PECsingle_use values can be seen as the contribution of one fumigation event to the concentrations of the global environment.
PECwater, single use	1.2×10^{-11} µg/L, (based on a single use of 3840 kg).
PECsediment, single use	2.6×10^{-16} mg/kg (based on a single use of 3840 kg).
PECair, single use	7.6×10^{-4} ng/m^3 (based on a single use of 3840 kg).
PECsoil, single use	1.3×10^{-16}mg/kg (based on a single use of 3840 kg).
	The best, worst case estimate of PECair_local can be found in

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section B7.8 (Doc III). In the justification for non-submission of data under section B7.8 the monitoring values of air concentrations at various positions around mills during the fumigation and venting processes are presented. From these, the maximum 24-hour time weighted average concentrations for a range distances from the mill have been estimated (see Table 7.8.1-1 of B7.8). The 90th percentile of 1.51 ppm (6.2 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, i.e. worst case PECair_local.

Evaluation by Competent Authorities for PT18	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	May 2007.
Materials and methods	X1: The term Upper Limit Ceiling Value should be changed to limit value. X2: This is true for European mills. X3: The value 3.09 measured at 10 m in study K27 was actually measured at 9.1 m. X4: See also new information submitted by the applicant as well as RMS's comments thereof, under section 7.3.1/02 in Doc III-A. X5: The PECs presented here were obtained by using the mean annual global production/emission volume (1.86 x 10^6 kg) during 1992-2000 as input value to the model. A new fugacity modelling has been submitted by the applicant (III-B7.5/02) using the estimated global emission volume for 2005 as input value. This modelling generated the following global PECs: PECwater: 1.3 x 10^{-11} mg/l PECsediment: 3.0 x 10^{-12} mg/kg PECair: 0.848 ng/m^3 (= 0.2 ppt) PECsoil: 1.5 x 10^{-13} mg/kg
Conclusion	Applicant's information is acceptable with consideration to the above given extra information, comments and/or amendments.
Reliability	Reliability indicator 2: Study conducted in accordance with generally accepted scientific principles, possibly with incomplete reporting or methodological deficiencies, which do not affect the quality of relevant results.
Acceptability	The information is acceptable with consideration to the above given extra information, comments and/or amendments. The information of the predicted concentrations of the global environment after an input of sulfuryl fluoride from a single fumigation event (PECsingle_use) is, however, of limited use.
Remarks	In Table A2.10 the term Upper Limit Ceiling Value should be changed to limit value.

Table A2.10: Workplace exposure / Inhalation exposure (use additional terminology from the TNsGs on Human exposure)

Exposure scenario	Workplace operation	PPE	Year(s) of measurement	Number of measurements	Type of measurements	Exposure concentration
Production	The biocidal product is manufactured in the USA. According to the TNsG Data Requirements, Ch.2, 2.10 and 6.6, for products manufactured outside the European Union, no details on production need to be included.					
Formulation	The biocidal product is manufactured in the USA. According to the TNsG Data Requirements, Ch.2, 2.10 and 6.6, for products manufactured outside the European Union, no details on production need to be included.					
Application MG3. /PT18.	ProFume is used as a fumigant for the control of stored product insect pests (SPIs) in emptied food processing facilities and emptied storage facilities.	SCBA – fumigators only. When working with gas cylinders during introduction of gas and when air concentrations exceed the Upper Limit Ceiling Value of 3 ppm.	Structural fumigation trials were conducted over a period of 2-3 years.	Measurements were taken at 11 independent structural fumigation trials.	Potential fumigator exposure was estimated using personal air samplers, fixed air samplers around each structure and also using hand-held equipment (e.g., Interscan).	Potential fumigator exposure in trials where SCBA was not used was, on average, 0.9 ppm.

Section A3 Physical and Chemical Properties of Active Substance

Annex Points IIA, III.3.1.1 to 3.13, Annex Points IIIA, III.1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14

Subsection	Year	Purity of AI used	Guideline No. and Method used	GLP	Result	Ref.	Reliability	Official use only	91/414/EEC Dossier Reference
3.1.1 Melting point	1957	N/A	No guideline - calculation	N	-136.7°C (calculation from heat of fusion which was determined cryoscopically)	A09	0	X1	IIA 2.1.1/01
3.1.2 Boiling point	2001	99.8%	EEC Method A2	Y	-54°C ± 1 °C	A15	1	X2	IIA 2.1.2/01
3.1.3 Relative density			No guideline - calculation	N	4.2 g/l at 20 °C and 1 atm, calculated from the Ideal Gas Law		0	X3	
3.2 Vapour pressure	1957 2001	99.35-99.41 mole %	No guideline - calculation	N	1611467 Pa at 20 °C	A09 A20	0	X4	IIA 2.1.1/01 IIA 2.3.1/01
3.2.1 Henry's law constant	2001		No guideline – calculation	N	Not required for substances that are gases. Calculated for other purposes as 1.56 atm m^3 mol^{-1} or 158142 Pa m^3 mol^{-1}.	A19	0	X5	IIA 2.3.2/01
3.3.1 State	2001	99.8%	Visual observation	Y	Gas	A15	1		IIA 2.4.1/01
3.3.2 Colour	2001	99.8%	Visual observation	Y	Colourless	A15	1		IIA 2.4.1/01
3.3.3 Odour					Not determined due to the hazardous nature of the test substance			X6	
3.4 Spectra for active substance	2000	99.8%	No guideline-mass spectroscopy	Y	2.5.1.d - MS Spectra available Fragment m/z 102, 83, 67	A08	1	X7	IIA 2.5.1/01
	2000	99.8%	No guideline-NMR spectroscopy		2.5.1.c - ^{19}F NMR Spectra available ^{19}F chemical shift of 34.2 ppm	A11	1		IIA 2.5.1/02
	2001	99.8%	OECD No. 101	Y	2.5.1.a / 2.5.1.e - UV/Vis	A15	1	X8	IIA 2.5.1/03

Section A3 Physical and Chemical Properties of Active Substance

Annex Points IIA, III.3.1.1 to 3.13, Annex Points IIIA, III.1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14

Subsection	Year	Purity of AI used	Guideline No. and Method used	GLP	Result		Ref.	Reliability	Official use only	91/414/EEC Dossier Reference
					ε (dm^3/mol/cm) at 276 (purified water) = 37 ε (dm^3/mol/cm) at 290 (purified water) = 25 ε (dm^3/mol/cm) at 278 (0.1M HCl) = 61 ε (dm^3/mol/cm) at 290 (0.1MHCL) = 42					
	2001	99.8%	No guideline, IR spectroscopy	Y	2.5.1.b - IR 1502 cm^{-1} SO_2 asymmetric stretch 1268 cm^{-1} SO_2 symmetric stretch 840-900 cm^{-1} SF_2 asymmetric stretch 553 cm^{-1} SO_2 rock		A15	1		IIA 2.5.1/03
Spectra for impurities					No impurities of toxicological, ecotoxicological or environmental significance					
3.5 Water solubility	2001	99.8%	EEC Method A6	Y	**pH**	**Solubility mg/l**	A15	1	X9	IIA 2.6/01
					unbuffered	1040 (20°C)				
Solubility in the acidic/alkaline range					The molecule does not dissociate, no pH effect is anticipated.					

Section A3 Physical and Chemical Properties of Active Substance

Annex Points IIA, III.3.1.1 to 3.13, Annex Points IIIA, III.1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14

Subsection	Year	Purity of AI used	Guideline No. and Method used	GLP	Result		Ref.	Reliability	Official use only	91/414/EEC Dossier Reference
3.6 Dissociation constant			OECD Guideline 112		Not required - test substance does not reversibly ionize				X10	
3.7 Solvent solubility	2001	99.8%	Purging the solvents with the test substance	Y	**Solvent**	Solubility g/l (20°C)	A15	1	X11	IIA 2.7/01
					n-heptane	**22**				
					xylene	**25**				
					1,2-dichloroethane	**25**				
					methanol	**33**				
					acetone	**71**				
					ethyl acetate	**59**				
3.8 Stability in organic solvents used in biocidal products					The active ingredient is the product. There are no further co-formulants in the biocidal product.				X12	
3.9 Partition coefficient	2001	99.8%	EEC Method A8	Y	Log K_{ow} = 0.14		A15	1	X13	IIA 2.8/01
Effect of pH on the n-octanol/water partition					The molecule does not dissociate, no effect on pH is anticipated.				X14	

Section A3 Physical and Chemical Properties of Active Substance

Annex Points IIA, III.3.1.1 to 3.13, Annex Points IIIA, III.1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14

Subsection	Year	Purity of AI used	Guideline No. and Method used	GLP	Result	Ref.	Reliability	Official use only	91/414/EEC Dossier Reference
coefficient									
3.10 Temperature of decomposition					Not required -No decomposition or sublimation occurs at the melting or boiling temperature. It is gas.			X15	
3.11 Flammability					Non-flammable according to ASTME681 and consistent with the fact that Sulphur, the element capable of being oxidised, is already fully oxidised and no reaction is expected to occur.	A28		X16	IIA 2.11/01
3.11 Auto-flammability					Test substance is non flammable and will not ignite in air. Sulphur, the element capable of being oxidised, is already fully oxidised and no reaction is expected to occur.	A28		X17	IIA 2.11/01
3.12 Flash point					Not required-test substance is a gas. EEC Method A9 is applicable to liquids or material with melting point less than 40°C			X18	
3.13 Surface tension					Surface tension is measured for an aqueous solution. This test is not applicable for a gas.			X19	
3.14 Viscosity					This test is required for a liquid substance. Sulfuryl fluoride is a gas, therefore this test is not applicable.			X20	

Section A3 Physical and Chemical Properties of Active Substance

Annex Points IIA, III.3.1.1 to 3.13, Annex Points IIIA, III.1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14

Subsection	Year	Purity of AI used	Guideline No. and Method used	GLP	Result	Ref.	Reliability	Official use only	91/414/EEC Dossier Reference
3.15 Explosive properties					Non-explosive. Sulphur, the element capable of being oxidised, is already fully oxidised and no reaction is expected to occur. Test substance is a gas. Method A14 is for a solid or a pasty substance if they present a danger of explosion when submitted to the effect of a flame or to shock or whether a liquid substance presents a danger of explosion when submitted to the effect of a flame or shock.	A28		X21	IIA 2.13/01
3.16 Oxidizing properties					Not tested.			X22	
3.17 Reactivity towards container material					Steel cylinders have been used for over 40 years of commercial use in the US.			X23	

Section A3 **Physical and Chemical Properties of Active Substance**

Annex Points IIA, III 3.1.1 to 3.13, Annex Points IIIA, III 1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	October 2004
Evaluation of data submitted under section A3	**3.1.1 Melting point** Materials and Method X1: The melting point was experimentally determined, not calculated, by the following procedure: A freezing point apparatus was utilized which automatically recorded a freezing curve from which the freezing point was determined. The study was performed 1957, and is therefore not in compliance with GLP and is not conducted in accordance with recommended OECD or EC methods. Moreover the test is insufficiently reported. Results X1: The reported freezing point is the judged value for a 100% pure a.i. taken from the experimentally obtained value -136.83 °C for a sample with the purity of 99.41 mol%. Reliability X1: Reliability indicator 3: Study with major methodological and/or reporting deficiencies. The low reliability indicator allocated is due to the major deficiency in the reporting of the study from 1957. Acceptability X1: Since the used test method is insufficiently described, the validity of the reported value cannot be completely assessed. However, the reported melting point is sufficiently low that any discrepancy from the true value which originates from the use of an obsolete test method should be irrelevant. The used method and the obtained result are therefore considered to be acceptable. **3.1.2 Boiling point** Materials and Method X2: The boiling point was determined using a freezing point apparatus (Stanhope Seta Ltd.) filled with acetone and dry ice as freezing media. The temperature at which sulfuryl fluoride boiled was recorded together with the barometric pressure. The obtained result is in good agreement with the quoted boiling of sulfuryl fluoride at atmospheric pressure of -55.4 °C in literature ("The Merck Index, 11th Edition Published by Merck & Co., Inc.). The determination was performed at 1001 mbar instead of 1013 mbar (1 atm). This should however not significantly have affected the result. Results The applicant's version is adopted. Reliability Reliability indicator 1: Study conducted in compliance with agreed protocols, with no or minor deviations from standard test guidelines and/or minor methodological deficiencies, which do not affect the quality of relevant results. Acceptability

Section A3	Physical and Chemical Properties of Active Substance
Annex Points IIA, III 3.1.1 to 3.13, Annex Points IIIA, III 1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14	

The used method and the obtained results are acceptable.

3.1.3 Relative density

Materials and Method

X3: In accordance with the Technical Notes for Guidance on Data Requirements (TNsG) the density (i.e. not the relative density) of the gas sulfuryl fluoride was calculated using the Ideal Gas Law.

Results

The applicant's version is adopted.

Reliability

Reliability indicator 0: Not applicable since no study was performed for the relative density.

Acceptability

The calculation is acceptable.

3.2 Vapour pressure

Materials and Method

X4: In the study from 1957 the boiling point at eight pressures between 73 and 785 mm Hg was measured.

The set of measured boiling points and corresponding pressures were inserted into Antoine's equation (log(P)=A-B/(T+C)) where after the parameters A, B and C were calculated. This resulted in the vapour pressure curve:

log (P)=7.094-797.34/(T+244.78)

This vapour pressure curve was then utilized in the study from 2001 to calculate (extrapolate) the vapour pressure at 20 °C.

The study was performed 1957, and is therefore not in compliance with GLP and is not conducted in accordance with recommended OECD or EC methods. Moreover the method used is insufficiently described since only the above information is given in the study report together with the results.

Results

The applicant's version is adopted.

Reliability

X4: Reliability indicator 3: Study with major methodological and/or reporting deficiencies.

The low reliability indicator allocated, is due to the major deficiency in the reporting of the study from 1957.

Acceptability

X4: Since the used test method is insufficiently described, the validity of the reported value cannot be completely assessed. However the method used (see Materials and Method above) is a standard procedure to determine the vapour pressure. Moreover a comparison of the obtained vapour pressure with vapour pressure data for molecules having similar chemical properties (i.e. molar weight, polarity and boiling point) indicates that the reported value is of the right magnitude (e.g. the vapour pressures of bromtrifluoromethane, CAS-No: 75-63-8 and HFC 125 (C_2HF_5), CAS-No: 354-33-6 are 1.6 MPa and 1.4 MPa respectively; source: The Physical Properties Database (PHYSPROP), Syracuse Research Corporation)

Section A3 Physical and Chemical Properties of Active Substance

Annex Points IIA, III 3.1.1 to 3.13, Annex Points IIIA, III 1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14

The used method and the obtained results are therefore considered to be acceptable, despite the low reliability indicator.

3.2.1 Henry's law constant

Materials and Method
The applicant's version is adopted.

Results
The applicant's version is adopted.

Reliability
X5: No special study is performed for the Henry's law constant. However, the result is calculated from the experimentally obtained results on the vapour pressure and the water solubility and a reliability indicator can therefore be applied.

Reliability indicator 3: Study with major methodological and/or reporting deficiencies.

The low reliability indicator allocated is due to the major deficiency in the reporting of the study from 1957.

Acceptability

X5: Since there is no requirement to determine the Henry's law constant for gaseous substances no further action is taken, despite the low reliability indicator.

3.3.1 Physical state

Materials and Method
The applicant's version is adopted.

Results
The applicant's version is adopted.

Reliability
Reliability indicator 1: Study conducted in compliance with agreed protocols, with no or minor deviations from standard test guidelines and/or minor methodological deficiencies, which do not affect the quality of relevant results.

Acceptability
The used method and the obtained results are acceptable.

3.3.2 Colour

Materials and Method
The applicant's version is adopted.

Results
The applicant's version is adopted.

Reliability
Reliability indicator 1: Study conducted in compliance with agreed protocols, with no or minor deviations from standard test guidelines and/or minor methodological deficiencies, which do not affect the quality of relevant results.

Acceptability
The used method and the obtained results are acceptable.

3.3.3 Odour

X6: See the justification below the evaluation box.

3.4 Spectra for active substance

Materials and Method
The applicant's version is adopted.

Section A3 Physical and Chemical Properties of Active Substance

Annex Points IIA, III 3.1.1 to 3.13, Annex Points IIIA, III 1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14

Results

NMR spectroscopy

The applicant's version is adopted

Mass spectroscopy

X7: The obtained fragments were identified as:

m/z

102 (molecular ion)

83 ($[SO_2F]^+$)

67 ($[SOF]^+$)

UV/Vis

X8: Absorption maxima were found for the solution in purified water (pH 2.0) and for the solution in water + HCl (pH 1.3) at 276 nm and at 278 nm respectively. Included in the table are also the molar absorption coefficients at a specified wavelength 290 nm. The absorption bands were not present in the basic system (pH 12.4) and this was considered to be due to the fact that sulfuryl fluoride is rapidly hydrolysed in aqueous alkali.

IR spectroscopy

The applicant's version is adopted

Reliability

Reliability indicator 1: Study conducted in compliance with agreed protocols, with no or minor deviations from standard test guidelines and/or minor methodological deficiencies, which do not affect the quality of relevant results.

3.5 Water solubility

Materials and Method

X9: Since the test material is a gas, the solubility in water was determined by a method based on purging purified water with the material for varying periods of time until analysis of the test solutions demonstrated that the concentration had reached equilibrium.

Results

X9: The water solubility was determined to be 1.04 ± 0.12 g/l at 20 °C in unbuffered purified water. The raw data file shows that the mean pH of the measured solutions was approximately 2.5. This means that the result could be seen as the solubility of sulfuryl fluoride in water at a pH of approximately 2.5.

The pH dependence of the solubility in water was not examined as sulfuryl fluoride does not dissociate. However as shown in Document III-A.7 sulfuryl fluoride hydrolyses very rapidly under alkaline conditions (DT_{50}=4.0 min at pH 9), which means that a significantly higher solubility in water in the alkaline range is to be expected.

Reliability

Reliability indicator 1: Study conducted in compliance with agreed protocols, with no or minor deviations from standard test guidelines and/or minor methodological deficiencies, which do not affect the quality of relevant results.

Acceptability

The used method and the obtained results are acceptable.

3.6 Dissociation constant

X10: See the justification below the evaluation box.

3.7 Solvent solubility

Section A3 Physical and Chemical Properties of Active Substance

Annex Points IIA, III 3.1.1 to 3.13, Annex Points IIIA, III 1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14

Materials and Method

X11: The method used for the water solubility (see above) was employed for the solvent solubility.

Results

X11: The solubility in n-octanol was also determined (14 g/l).

Reliability

Reliability indicator 1: Study conducted in compliance with agreed protocols, with no or minor deviations from standard test guidelines and/or minor methodological deficiencies, which do not affect the quality of relevant results.

Acceptability

The used method and the obtained results are acceptable.

3.8 Stability in organic solvents used in biocidal products

X12: See the justification below the evaluation box.

3.9 Partition coefficient

Materials and Method

X13: Since sulfuryl fluoride is a gas a modified version of the "shake-flask"-method (OECD 108) was utilized. A saturated stock solution in water (pre-saturated with n-octanol) was prepared by purging the water with sulfuryl fluoride. This stock solution was then mixed and equilibrated with water (pre-saturated with n-octanol) and n-octanol (pre-saturated with water) in different ratios and the layers were then separated and the partition coefficient was subsequently calculated.

Results

The used method and the obtained results are acceptable.

Reliability

Reliability indicator 1: Study conducted in compliance with agreed protocols, with no or minor deviations from standard test guidelines and/or minor methodological deficiencies, which do not affect the quality of relevant results.

Acceptability

The used method and the obtained results are acceptable.

3.9 Effect of pH on the n-octanol/water partition coefficient

X14: This parameter was not studied since sulfuryl fluoride does not dissociate. However, as sulfuryl fluoride rapidly hydrolyses under alkaline conditions a significantly lower log P_{ow} is to be expected for the alkaline range.

3.10 Temperature of decomposition

X15: See the justification below the evaluation box.

3.11 Flammability

Materials and Method

X16: The used method ASTM E681 is equivalent to the recommended EC method A.11. The testing conditions were in the concentration range 1.1 to 50.5 volume% in air at 24 °C. The purity of the test material was 99%.

The study report does not state whether the study was performed in compliance with GLP or not.

Results

X16: No flame propagated under the conditions used. The test material was therefore not considered to be flammable.

Reliability

Section A3	Physical and Chemical Properties of Active Substance
Annex Points IIA, III 3.1.1 to 3.13, Annex Points IIIA, III 1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14	

X16: Reliability indicator 2: Study conducted in accordance with generally accepted scientific principles, possibly with incomplete reporting or methodological deficiencies, which do not affect the quality of relevant results.

Acceptability
The used method and the obtained result are acceptable.

3.11 Auto-flammability

X17: See the justification below the evaluation box.

3.12 Flash point

X18: See the justification below the evaluation box.

3.13 Surface tension

X19: The surface tension is not addressed for the active substance but it is addressed for the product. Since the product solely contains the technical active substance the results on the surface tension can be adopted from document III-B 3.10.1.

Materials and Method
The method used was EEC Method A5. The purity of the test material was 99.8%.

Results
The surface tension was determined to be 67.5 mN/m (90% saturated solution) at 20 °C.

Reliability
Reliability indicator 1: Study conducted in compliance with agreed protocols, with no or minor deviations from standard test guidelines and/or minor methodological deficiencies, which do not affect the quality of relevant results.

Acceptability
The used method and the obtained results are acceptable.

3.14 Viscosity

X20: See the justification below the evaluation box.

3.15 Explosive properties

X21: See the justification below the evaluation box.

3.16 Oxidizing properties

X22: See the justification below the evaluation box.

3.17 Reactivity towards container material

X23: This parameter is not addressed with a study. However a study was performed to calculate the average corrosion rate for the steel cylinders used to transport and store the biocidal product Vikane. This study is used to address the requirements in Annex point IIB, III.3.7 (shelf-life).

Since the product solely contains the technical active substance this study can also be evaluated for this parameter.

Materials and Method
The following method was used:
A statistical sampling of the thickness measurements from 200 cylinders was taken and used to calculate cylinder corrosion rates.

Results
The obtained result was:
The average corrosion rate calculated was less than 2 mils per year (≈0.05 mm/year).

Section A3 Physical and Chemical Properties of Active Substance

Annex Points IIA, III 3.1.1 to 3.13, Annex Points IIIA, III 1 to 2 and TnsG Chapter 3, Part A, Point 3.6 and Point 3.14

	Reliability Reliability indicator 2: Study conducted in accordance with generally accepted scientific principles, possibly with incomplete reporting or methodological deficiencies, which do not affect the quality of relevant results. Acceptability The used method and the obtained results are acceptable.

Justifications for non-submission of data under Section A3

Section A3.3.3 Annex Point IIA, III.3.3	**Odour**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [x]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Not determined due to hazardous nature of test substance. Sulfuryl fluoride is toxic by inhalation. Please refer to A6.1.3. Inhalation Toxicity.	
Undertaking of intended data submission [ ]	No study planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2004	
Evaluation of applicant's justification	Due to the hazardous nature of sulfuryl fluoride it is not possible to determine the odour by olfactory assessment.	
Conclusion	The justification is acceptable.	
Remarks	There are no further remarks.	

Section A3.6 TnsG Chapter 3, Part A, Point 3.6	Dissociation constant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [x] Other justification [ ]	
Detailed justification:	Not required - test substance does not reversibly ionize.	
Undertaking of intended data submission [ ]	No study planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2004	
Evaluation of applicant's justification	Sulfuryl fluoride does not reversibly ionize, which means that a study on the dissociation constant is not required. However, in alkaline aqueous solutions it undergoes rapid hydrolysis.	
Conclusion	The justification is acceptable.	
Remarks	There are no further remarks.	

Section A3.8 Annex Point IIIA, III.2	Stability in organic solvents used in biocidal products and identity of relevant break down products	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [x]	
Limited exposure [ ]	Other justification [ ]	
Detailed justification:	The active ingredient sulfuryl fluoride is also the biocidal product. There are no formulants used to make the product. Therefore there are no organic solvents used in the biocidal product either.	
Undertaking of intended data submission [ ]	No study planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2004	
Evaluation of applicant's justification	Sulfuryl fluoride is not used together with any organic solvents. This data requirement is therefore not needed.	
Conclusion	The justification is acceptable.	
Remarks	There are no further remarks.	

Section A3.10 Annex Point IIA, III.3.7	Thermal stability, identity of relevant breakdown products	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [x] Other justification [ ]	
Detailed justification:	Not required - No decomposition or sublimation occurs at the melting or boiling temperature. It is gas.	
Undertaking of intended data submission [ ]	No study planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2004	
Evaluation of applicant's justification	In addition to the justification above the applicant also submitted data from a computer based test on the thermal stability of sulfuryl fluoride using "CHETAH: ASTM Computer Program for Chemical Thermodynamic and Energy Release Evaluation Version 7.2" (American Society for Testing and Materials, West Conshohocken, PA, 1998.). The potential of sulfuryl fluoride to decompose was assessed for the following two possible degradation routes: (1) SO_2F_2 (g) → SO_2 (g) + F_2 (g) (2) SO_2F_2 (g) → 1/3 SF_6 (g) + 2/3 SO_3 (g) The outcome was negative in both cases up to 1500 K (1227 °C), which is the highest temperature allowed by the program. Sulfuryl fluoride is therefore considered to be thermally stable and indicates that no further testing is needed.	
Conclusion	The test according to ASTM CHETAH 7.2 (see above) is acceptable and no further testing is needed.	
Remarks	There are no further remarks.	

Section A3.11 Annex Point IIA, III.3.8	Auto-flammability	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	Auto-flammability (also called Auto-ignition) is the lowest temperature at which the material will spontaneously ignite in the absence of an external ignition source, such as a spark or flame. It is covered by EC A.15 or ASTM Method E659 where a sample of the test material is introduced into a uniformly heated flask and observed for 10 minutes or until ignition occurs. Because sulfuryl fluoride did not burn in air in the presence of an external ignition source (no flammable limits via ASTM E681 (or EC A.11)), then, by definition, it cannot spontaneously burn in the absence of an ignition source. (MSH 12/2/2004).	
Undertaking of intended data submission [ ]	No study planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	December 2004	
Evaluation of applicant's justification	Since sulfuryl fluoride was shown to be non flammable it is not expected to be auto-flammable and the justification is hereby acceptable.	
Conclusion	The justification is acceptable.	
Remarks	There are no further remarks.	

Section A3.12 Annex Point IIA, III.3.9	Flash-point	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [x] Other justification [ ]	
Detailed justification:	Not required-test substance is a gas. EEC Method A9 is applicable to liquids or material with melting point less than 40°C Flash point is defined for a vapour-liquid system, not for vapours. Because sulfuryl fluoride is a liquid only below its boiling point of -55 degC, its flash point cannot be measured. Mercury freezes at -38.87 degC and this defines the lowest possible temperature limit of any instrument using a mercury thermometer.*** ***Background References: Here are the descriptions of two most applicable ASTM Flash Point Test Methods with regard to low temperature measurements: ASTM D-56 - Tag Closed Cup Flash Point Tester This device places the sample in a metal cup that is immersed in a liquid bath. The medium in this bath is typically water. The temperature range of the method can be extended by changing the medium to a 1:1 glycol water mixture. Paragraph 8.3, Note 5 of this method states: Due to possible difficulty in maintaining the prescribed rate of temperature rise and due to the formation of ice on the lid, results by this method for samples having flash points below 0C (32 F), may be unreliable. Trouble due to ice formation on the slide can be minimized by carefully lubricating the slide shutter with high-vacuum silicone lubricant. ASTM 3828 - Flash Point by Small Scale Closed Tester This device can conduct measurements below ambient temperature also. These instruments typically come equipped with mercury thermometers. This is what this ASTM method says about low temperature measurements: For Expected Flash Points Below Ambient: 12.9.1 The instrument power switch is to be in the off position. Fill the refrigerant-charged cooling block with a suitable material (see Note 7). Raise the lid and shutter assembly, and position the base of the block in the specimen cup, being careful not to dent or mar the cup. When the thermometer reaches a temperature of 5 to 10C (10 to 20F) (Caution - See Note 7) below the expected flash point, remove the cooling block and quickly dry the cup and underside of the lid and shutter with a paper tissue to remove any moisture. Immediately close the lid and shutter assembly and secure. Prepare to introduce the portion using the syringe, both of which have been pre-cooled to a temperature below the expected temperature. Note 6 - When the target or specification temperature is not less than 5C crushed ice and water can be used as a charging (cooling) fluid. If below 5C a suitable charging (cooling) fluid is solid carbon dioxide (dry ice)	

Section A3.12 Annex Point IIA, III.3.9	Flash-point
	and acetone (WARNING - see Note 8). If the refrigerant-charged cooling module is unavailable refer to the manufacturer's instruction manual for alternative methods of cooling. Note 7 - CAUTION - Do not cool the sample block below -38C, the freezing point of mercury. Note 8 - Acetone is extremely flammable. Dry ice must not contact the eyes or skin
Undertaking of intended data submission [ ]	No study planned.
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	December 2004.
Evaluation of applicant's justification	There are no common techniques to conduct a flash-point measurement on sulfuryl fluoride, since it has a boiling point of -54 °C (i.e. it has to be a liquid-vapour system). The applicant's justification is therefore acceptable.
Conclusion	The applicant's justification is acceptable.
Remarks	There are no further remarks.

Section A3.14 TnsG Chapter 3, Part A, Point 3.14	Viscosity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [x] Other justification [ ]	
Detailed justification:	Test substance is a gas and not a newtonian liquid. It is a newtonian liquid under pressure. Standard viscosity methods are not applicable.	
Undertaking of intended data submission [ ]	No study planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2004	
Evaluation of applicant's justification	The viscosity is only relevant for substances which are liquids at STP (Standard Temperature and Pressure). This data requirement is therefore not needed for sulfuryl fluoride.	
Conclusion	The justification is acceptable.	
Remarks	There are no further remarks.	

Section A3.15 Annex Point IIA, III.3.11	Explosive properties	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [x] Other justification [ ]	
Detailed justification:	Non-explosive. Sulphur, the element capable of being oxidised, is already fully oxidised and no reaction is expected to occur. Test substance is a gas. Method A14 is for a solid or a pasty substance if they present a danger of explosion when submitted to the effect of a flame or to shock or whether a liquid substance presents a danger of explosion when submitted to the effect of a flame or shock.	
Undertaking of intended data submission [ ]	No study planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2004.	
Evaluation of applicant's justification	In addition to the justification above the applicant has also submitted data from a computer based test on the explosive properties of sulfuryl fluoride using ASTM CHETAH 7.1 ("the Dow-modified computer program for chemical thermodynamic and energy release evaluation", Downey, J., Frurip, D., Grant, N., LaBarge, M., Marks, M, Syverud, A., 1993). This test indicated that sulfuryl fluoride is not explosive (i.e. will not violently decompose if subjected to the proper conditions) since the maximum heat of decomposition was calculated to be 0.2302 kcal/g. The outcome of this test together with the justification above show that no further testing is needed.	
Conclusion	The applicant's justification and the submitted computer based test according to ASTM CHETAH 7.1 (see above) are acceptable.	
Remarks	There are no further remarks.	

Section A3.16 Annex Point IIA, III.3.12	Oxidizing properties	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [x] Other justification [ ]	
Detailed justification:	Sulphur, the element capable of being oxidised, is already fully oxidised and no reaction is expected to occur. Test substance is a gas, Method A17 is meant for solids.	X
Undertaking of intended data submission [ ]	No study planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2004	
Evaluation of applicant's justification	Oxidizing agents are easily reduced, not oxidized. However, since sulphur (VI+) is more stable than sulphur (IV) (e.g. SO_2 is a reducing agent) sulfuryl fluoride is not expected to have oxidizing properties.	
Conclusion	The justification is acceptable.	
Remarks	There are no further remarks.	

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 four lists below (numbered 1-4). 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 is not possible for the rapporteur to confirm the accuracy of this information. Sweden has earlier received those studies marked with Y(i) to support national product authorisation and according the Biocidal Products Ordinance (SFS 2000:338) section 14, those studies may be used for the benefit of other applicants only after 13 May 2010, while studies marked with Y(ii) may be used for the benefit of another applicant only after the expiry of a period of ten years from the date the active substance was first listed in Annex I or IA to the Biocides Directive 98/8/EC.

Data Owner:	D = Dow AgroSciences
	P= Public domain

1. List of Studies Sorted by Section Number (98/8)

98/8 Section Number (IIIA)	91/414 Annex Point	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/01	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	GH-C 2977 / Derbi 15114	A05
2.7 2.8	IIA 1.11/02	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	FA&PC Number 003109	O08

98/8 Section Number (IIIA)	91/414 Annex Point	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/03	[redacted]	Chemical Purity, Analytical Report Number: 91-232. Vikane 18 month inhalation CD-1 mice and Vikane Reproduction	[redacted]	N	N	N	Y (ii)	D	91-232	November 1991	91-232	OT04
2.7 2.8	IIA 1.11/04	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	98-412	OT01
2.7 2.8	IIA 1.11/05	Langvardt, P.	Analytical Data Sheet 88-226, Vikane Inhalation	The Dow Chemical Company	N	N	N	Y (ii)	D	88-226	October 1988	88-226	OT10
2.7 2.8	IIA 1.11/06	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	90-137	OT08
2.7 2.8	IIA 1.11/07	[redacted]	Chemical Purity, Analytical Report Number: 91-194.Vikane 18 month inhalation CD-1 mice	[redacted]	N	N	N	Y (ii)	D	91-194	October 1991	91-194	OT05
2.7 2.8	IIA 1.11/08	[redacted]	Chemical Purity, Analytical Report Number: 91-100. Vikane 18 month inhalation CD-1 mice.	[redacted]	N	N	N	Y (ii)	D	91-100	May 1991	91-100	OT07
2.7 2.8	IIA 1.11/09	[redacted]	Chemical Purity, Analytical Report Number: 93-54, Vikane 18 months mouse, 2-year rat and 1 year dog chronic inhalation studies	[redacted]	N	N	N	Y (ii)	D	93-54	February 1993	93-54	OT02

98/8 Section Number (IIIA)	91/414 Annex Point	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/10	[redacted]	Chemical Purity, Analytical Report Number: 92-45, Vikane chronic/onco. Rat& mouse inhalation and Vikane 1-year chronic dogs	[redacted]	N	N	N	Y (ii)	D	92-45	March 1992	92-45	OT03
2.7 2.8	IIA 1.11/11	[redacted]	Chemical Purity, Analytical Report Number: 92-163. Vikane 18 month mouse, 2-year rat and 1-year dog chronic inhalation studies	[redacted]	N	N	N	Y (ii)	D	92-163	July 1992	92-163	OT06
2.7 2.8	IIA 1.11/12	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	ML-AL 92-050933	OT09
2.7 2.8	IIA 1.11/13	Anon	Vikane Analysis – K-16399-018	The Dow Chemical Company, Midland, Mi, USA	N	N	N	Y (ii)	D	K-16399-018	April 1980	K-16399-018	OT11
2.7 2.8	IIA 1.11/14	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	K-016399-023/K-16399-(14)	OT12
2.7 2.8	IIA 1.11/15	Campbell, R.A.	Composition Report, Vikane UDS Assay	The Dow Chemical Company	N	N	N	Y (ii)	D	GT-45-91	May 1991	K-016399-043	OT13

98/8 Section Number (IIIA)	91/414 Annex Point	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/16	Roll, H.	Vikane Product Release, Lot Number 141	The Dow Chemical Company	N	N	N	Y (ii)	D	HET-K-16399-13	March 1979	HET-K-16399-13	OT14
2.7 2.8	IIA 1.11/17	Ammons, R.W.	Vikane Product Release, Lot number 874	The Dow Chemical Company	N	N	N	Y (ii)	D	K-016399-037	February 1990	K-016399-037	OT15
2.7 2.8	IIA 1.11/18	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	K-016399-022/K-016399-025	OT16
3.1.1	IIA 2.1.1/01	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	SSR 226-624	A09
3.1.2, 3.3.1, 3.4.2, 3.5, 3.7, 3.9, 3.13	IIA 2.1.2/01 2.4.1/01 2.5.1/03 2.6/01 2.7/01 2.8/01 2.14/01	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	NAFST460	A15

98/8 Section Number (IIIA)	91/414 Annex Point	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	Dow AgroSciences Report No	Ref.
3.2	IIA 2.1.1/01	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	SSR 226-624	A09
3.2	IIA 2.3.1/01	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	GH-C 5319	A20
3.2.1	IIA 2.3.2/01	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	GH-C 5306	A19
3.4.1, 3.4.2, 3.4.3, 3.4.4	IIA 2.5.1/01	Russell, M.W	Determination of the purity and identity of Sulfuryl Fluoride, TSN101693	Dow AgroSciences	Y	N	N	Y (ii)	D	NAFST244	May 2000	NAFST244	A08
3.4.3	IIA 2.5.1/02	Ghaoui, L.H., Thornburgh S.	Nuclear Magnetic Resonance Study for Sulfuryl Fluoride	Dow AgroSciences, Indianapolis	N	N	N	Y (ii)	D	FOR00006	August 2000	FOR00006	A11

98/8 Section Number (IIIA)	91/414 Annex Point	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	Dow AgroSciences Report No	Ref.
3.11 3.15 3.16	IIA 2.11/01 2.13/01 2.15/01	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	NAFST 594	A28

2. List of Studies Sorted by 91/414 Annex Point

98/8 Section Number (IIIA)	91/414 Annex Point	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/01	Stolz, W. L.	Series 62: Analysis and Certification of Product ingredients of VIKANE* Gas Fumigant	DowElanco Indianapolis	Y	N	N	Y (i)	D	FOR92080	March 1993	GH-C 2977 / Derbi 15114	A05
2.7 2.8	IIA 1.11/02	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	FA&PC Number 003109	O08
2.7 2.8	IIA 1.11/03	[redacted]	Chemical Purity, Analytical Report Number: 91-232. Vikane 18 month inhalation CD-1 mice and Vikane Reproduction	[redacted]	N	N	N	Y (ii)	D	91-232	November 1991	91-232	OT04
2.7 2.8	IIA 1.11/04	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	98-412	OT01
2.7 2.8	IIA 1.11/05	Langvardt, P.	Analytical Data Sheet 88-226, Vikane Inhalation	The Dow Chemical Company	N	N	N	Y (ii)	D	88-226	October 1988	88-226	OT10
2.7 2.8	IIA 1.11/06	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	90-137	OT08

98/8 Section Number (IIIA)	91/414 Annex Point	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/07	[redacted]	Chemical Purity, Analytical Report Number: 91-194.Vikane 18 month inhalation CD-1 mice	[redacted]	N	N	N	Y (ii)	D	91-194	October 1991	91-194	OT05
2.7 2.8	IIA 1.11/08	[redacted]	Chemical Purity, Analytical Report Number: 91-100. Vikane 18 month inhalation CD-1 mice.	[redacted]	N	N	N	Y (ii)	D	91-100	May 1991	91-100	OT07
2.7 2.8	IIA 1.11/09	[redacted]	Chemical Purity, Analytical Report Number: 93-54, Vikane 18 months mouse, 2-year rat and 1 year dog chronic inhalation studies	[redacted]	N	N	N	Y (ii)	D	93-54	February 1993	93-54	OT02
2.7 2.8	IIA 1.11/10	[redacted]	Chemical Purity, Analytical Report Number: 92-45, Vikane chronic/onco. Rat & mouse inhalation and Vikane 1-year chronic dogs	[redacted]	N	N	N	Y (ii)	D	92-45	March 1992	92-45	OT03
2.7 2.8	IIA 1.11/11	[redacted]	Chemical Purity, Analytical Report Number: 92-163. Vikane 18 month mouse, 2-year rat and 1-year dog chronic inhalation studies	[redacted]	N	N	N	Y (ii)	D	92-163	July 1992	92-163	OT06
2.7 2.8	IIA 1.11/12	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	ML-AL 92-050933	OT09

98/8 Section Number (IIIA)	91/414 Annex Point	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/13	Anon	Vikane Analysis – K-16399-018	The Dow Chemical Company, Midland, Mi, USA	N	N	N	Y (ii)	D	K-16399-018	April 1980	K-16399-018	OT11
2.7 2.8	IIA 1.11/14	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	K-016399-023/K-16399-(14)	OT12
2.7 2.8	IIA 1.11/15	Campbell, R.A.	Composition Report, Vikane UDS Assay	The Dow Chemical Company	N	N	N	Y (ii)	D	GT-45-91	May 1991	K-016399-043	OT13
2.7 2.8	IIA 1.11/16	Roll, H.	Vikane Product Release, Lot Number 141	The Dow Chemical Company	N	N	N	Y (ii)	D	HET-K-16399-13	March 1979	HET-K-16399-13	OT14
2.7 2.8	IIA 1.11/17	Ammons, R.W.	Vikane Product Release, Lot number 874	The Dow Chemical Company	N	N	N	Y (ii)	D	K-016399-037	February 1990	K-016399-037	OT15
2.7 2.8	IIA 1.11/18	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	K-016399-022/K-016399-025	OT16
3.1.1 3.2	IIA 2.1.1/01	McDonald, R.A, Hildenbrand, D.L.	Some Physical Properties of Sulfuryl Fluoride	Dow Chemical Company	N	N	N	N (ii)	D	SSR 226-624	June 1957	SSR 226-624	A09

98/8 Section Number (IIIA)	91/414 Annex Point	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	Dow AgroSciences Report No	Ref.
3.1.2, 3.3.1, 3.4.2, 3.5, 3.7, 3.9, 3.13	IIA 2.1.2/01 2.4.1/01 2.5.1/03 2.6/01 2.7/01 2.8/01 2.14/01	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	NAFST460	A15
3.11, 3.15 3.16	IIA 2.11/01 2.13/01 2.15/01	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	NAFST 594	A28
3.2	IIA 2.3.1/01	Krieger, M.S.	Vapour 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	GH-C 5319	A20

98/8 Section Number (IIIA)	91/414 Annex Point	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	Dow AgroSciences Report No	Ref.
3.2.1	IIA 2.3.2/01	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	GH-C 5306	A19
3.4.1, 3.4.2, 3.4.3, 3.4.4	IIA 2.5.1/01	Russell, M.W	Determination of the purity and identity of Sulfuryl Fluoride, TSN101693	Dow AgroSciences	Y	N	N	Y (ii)	D	NAFST244	May 2000	NAFST244	A08
3.4.3	IIA 2.5.1/02	Ghaoui, L.H., Thornburgh S.	Nuclear Magnetic Resonance Study for Sulfuryl Fluoride	Dow AgroSciences, Indianapolis	N	N	N	Y (ii)	D	FOR00006	August 2000	FOR00006	A11

3. List of Studies Sorted by Author

98/8 Section Number (IIIA)	91/414 Annex Section	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/17	Ammons, R.W.	Vikane Product Release, Lot number 874	The Dow Chemical Company	N	N	N	Y (ii)	D	K-016399-037	February 1990	K-016399-037	OT15
2.7 2.8	IIA 1.11/13	Anon	Vikane Analysis – K-16399-018	The Dow Chemical Company, Midland, Mi, USA	N	N	N	Y (ii)	D	K-16399-018	April 1980	K-16399-018	OT11
2.7 2.8	IIA 1.11/14	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	K-016399-023/K-16399-(14)	OT12
2.7 2.8	IIA 1.11/15	Campbell, R.A.	Composition Report, Vikane UDS Assay	The Dow Chemical Company	N	N	N	Y (ii)	D	GT-45-91	May 1991	K-016399-043	OT13
3.1.2, 3.3.1, 3.4.2, 3.5, 3.7, 3.9, 3.13	IIA 2.1.2/01 2.4.1/01 2.5.1/03 2.6/01 2.7/01 2.8/01 2.14/01	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	NAFST460	A15

98/8 Section Number (IIIA)	91/414 Annex Section	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	Dow AgroSciences Report No	Ref.
3.11, 3.15 3.16	IIA 2.11/01 2.13/01 2.15/01	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	NAFST 594	A28
3.4.3	IIA 2.5.1/02	Ghaoui, L.H., Thornburgh S.	Nuclear Magnetic Resonance Study for Sulfuryl Fluoride	Dow AgroSciences, Indianapolis	N	N	N	Y (ii)	D	FOR00006	August 2000	FOR00006	A11
2.7 2.8	IIA 1.11/04	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	98-412	OT01
2.7 2.8	IIA 1.11/18	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	K-016399-022/K-016399-025	OT16
3.2	IIA 2.3.1/01	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	GH-C 5319	A20

98/8 Section Number (IIIA)	91/414 Annex Section	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	Dow AgroSciences Report No	Ref.
3.2.1	IIA 2.3.2/01	Krieger, M.S.	Henry's Law Constant for Sulfuryl Fluoride (SO_2F_2)	Regulatory Laboratories – Indianapolis Lab, Dow AgroSciences, Indianapolis, Indiana, USA	N	N	N	Y (ii)	D	GH-C 5306	November 2001	GH-C 5306	A19
2.7 2.8	IIA 1.11/05	Langvardt, P.	Analytical Data Sheet 88-226, Vikane Inhalation	The Dow Chemical Company	N	N	N	Y (ii)	D	88-226	October 1988	88-226	OT10
2.7 2.8	IIA 1.11/03	[redacted]	Chemical Purity, Analytical Report Number: 91-232. Vikane 18 month inhalation CD-1 mice and Vikane Reproduction	[redacted]	N	N	N	Y (ii)	D	91-232	November 1991	91-232	OT04
2.7 2.8	IIA 1.11/06	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	90-137	OT08
2.7 2.8	IIA 1.11/07	[redacted]	Chemical Purity, Analytical Report Number: 91-194.Vikane 18 month inhalation CD-1 mice	[redacted]	N	N	N	Y (ii)	D	91-194	October 1991	91-194	OT05
2.7 2.8	IIA 1.11/08	[redacted]	Chemical Purity, Analytical Report Number: 91-100. Vikane 18 month inhalation CD-1 mice.	[redacted]	N	N	N	Y (ii)	D	91-100	May 1991	91-100	OT07

98/8 Section Number (IIIA)	91/414 Annex Section	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/09	[redacted]	Chemical Purity, Analytical Report Number: 93-54, Vikane 18 months mouse, 2-year rat and 1 year dog chronic inhalation studies	[redacted]	N	N	N	Y (ii)	D	93-54	February 1993	93-54	OT02
2.7 2.8	IIA 1.11/10	[redacted]	Chemical Purity, Analytical Report Number: 92-45, Vikane chronic/onco. Rat& mouse inhalation and Vikane 1-year chronic dogs	[redacted]	N	N	N	Y (ii)	D	92-45	March 1992	92-45	OT03
2.7 2.8	IIA 1.11/11	[redacted]	Chemical Purity, Analytical Report Number: 92-163. Vikane 18 month mouse, 2-year rat and 1-year dog chronic inhalation studies	[redacted]	N	N	N	Y (ii)	D	92-163	July 1992	92-163	OT06
3.1.1/3.2	IIA 2.1.1/01	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	SSR 226-624	A09
2.7 2.8	IIA 1.11/12	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	ML-AL 92-050933	OT09
2.7 2.8	IIA 1.11/16	Roll, H.	Vikane Product Release, Lot Number 141	The Dow Chemical Company	N	N	N	Y (ii)	D	HET-K-16399-13	March 1979	HET-K-16399-13	OT14

98/8 Section Number (IIIA)	91/414 Annex Section	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/02	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	FA&PC Number 003109	O08
3.4.1, 3.4.2, 3.4.3, 3.4.4	IIA 2.5.1/01	Russell, M.W	Determination of the purity and identity of Sulfuryl Fluoride, TSN101693	Dow AgroSciences	Y	N	N	Y (ii)	D	NAFST244	May 2000	NAFST244	A08
2.7 2.8	IIA 1.11/01	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	GH-C 2977 / Derbi 15114	A05

4. List of Studies Sorted by Reference Number

98/8 Section Number (IIIA)	91/414 Annex Section	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/01	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	GH-C 2977 / Derbi 15114	A05
3.4.1, 3.4.2, 3.4.3, 3.4.4	IIA 2.5.1/01	Russell, M.W	Determination of the purity and identity of Sulfuryl Fluoride, TSN101693	Dow AgroSciences	Y	N	N	Y (ii)	D	NAFST244	May 2000	NAFST244	A08
3.1.1/3.2	IIA 2.1.1/01	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	SSR 226-624	A09
3.4.3	IIA 2.5.1/02	Ghaoui, L.H., Thornburgh S.	Nuclear Magnetic Resonance Study for Sulfuryl Fluoride	Dow AgroSciences, Indianapolis	N	N	N	Y (ii)	D	FOR00006	August 2000	FOR00006	A11
3.1.2, 3.3.1, 3.4.2, 3.5, 3.7, 3.9, 3.13	IIA 2.1.2/01 2.4.1/01 2.5.1/03 2.6/01 2.7/01 2.8/01 2.14/01	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	NAFST460	A15

98/8 Section Number (IIIA)	91/414 Annex Section	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	Dow AgroSciences Report No	Ref.
3.2.1	IIA 2.3.2/01	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	GH-C 5306	A19
3.2	IIA 2.3.1/01	Krieger, M.S.	Vapour 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	GH-C 5319	A20
3.11, 3.15 3.16	IIA 2.11/01 2.13/01 2.15/01	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	NAFST 594	A28
2.7 2.8	IIA 1.11/02	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	FA&PC Number 003109	O08

98/8 Section Number (IIIA)	91/414 Annex Section	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/04	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	98-412	OT01
2.7 2.8	IIA 1.11/09	[redacted]	Chemical Purity, Analytical Report Number: 93-54, Vikane 18 months mouse, 2-year rat and 1 year dog chronic inhalation studies	[redacted]	N	N	N	Y (ii)	D	93-54	February 1993	93-54	OT02
2.7 2.8	IIA 1.11/10	[redacted]	Chemical Purity, Analytical Report Number: 92-45, Vikane chronic/onco. Rat & mouse inhalation and Vikane 1-year chronic dogs	[redacted]	N	N	N	Y (ii)	D	92-45	March 1992	92-45	OT03
2.7 2.8	IIA 1.11/03	[redacted]	Chemical Purity, Analytical Report Number: 91-232. Vikane 18 month inhalation CD-1 mice and Vikane Reproduction	[redacted]	N	N	N	Y (ii)	D	91-232	November 1991	91-232	OT04
2.7 2.8	IIA 1.11/07	[redacted]	Chemical Purity, Analytical Report Number: 91-194.Vikane 18 month inhalation CD-1 mice	[redacted]	N	N	N	Y (ii)	D	91-194	October 1991	91-194	OT05
2.7 2.8	IIA 1.11/11	[redacted]	Chemical Purity, Analytical Report Number: 92-163. Vikane 18 month mouse, 2-year rat and 1-year dog chronic inhalation studies	[redacted]	N	N	N	Y (ii)	D	92-163	July 1992	92-163	OT06

98/8 Section Number (IIIA)	91/414 Annex Section	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/08	[redacted]	Chemical Purity, Analytical Report Number: 91-100. Vikane 18 month inhalation CD-1 mice.	[redacted]	N	N	N	Y (ii)	D	91-100	May 1991	91-100	OT07
2.7 2.8	IIA 1.11/06	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	90-137	OT08
2.7 2.8	IIA 1.11/12	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	ML-AL 92-050933	OT09
2.7 2.8	IIA 1.11/05	Langvardt, P.	Analytical Data Sheet 88-226, Vikane Inhalation	The Dow Chemical Company	N	N	N	Y (ii)	D	88-226	October 1988	88-226	OT10
2.7 2.8	IIA 1.11/13	Anon	Vikane Analysis – K-16399-018	The Dow Chemical Company, Midland, Mi, USA	N	N	N	Y (ii)	D	K-16399-018	April 1980	K-16399-018	OT11
2.7 2.8	IIA 1.11/14	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	K-016399-023/K-16399-(14)	OT12
2.7 2.8	IIA 1.11/15	Campbell, R.A.	Composition Report, Vikane UDS Assay	The Dow Chemical Company	N	N	N	Y (ii)	D	GT-45-91	May 1991	K-016399-043	OT13

98/8 Section Number (IIIA)	91/414 Annex Section	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	Dow AgroSciences Report No	Ref.
2.7 2.8	IIA 1.11/16	Roll, H.	Vikane Product Release, Lot Number 141	The Dow Chemical Company	N	N	N	Y (ii)	D	HET-K-16399-13	March 1979	HET-K-16399-13	OT14
2.7 2.8	IIA 1.11/17	Ammons, R.W.	Vikane Product Release, Lot number 874	The Dow Chemical Company	N	N	N	Y (ii)	D	K-016399-037	February 1990	K-016399-037	OT15
2.7 2.8	IIA 1.11/18	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	K-016399-022/K-016399-025	OT16

Competent Authority Report

Work Programme for Review of Active Substances in Biocidal Products
Pursuant to Council Directive 98/8/EC

SULFURYL FLUORIDE (PT18)

DOCUMENT III-A6

Toxicological and Metabolic Studies

Rapporteur Member State: Sweden

Draft June 2007
Draft Final January 2008
Final April 2008

KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

Table of Contents; DOC III-A6

Please note:

- **The dossier on sulfuryl fluoride submitted under Directive 98/8/EC contained studies and information prepared originally for the dossier submitted under Directive 91/414/EEC. This was accepted by the RMS since the compilation of the dossier was made at an early stage, i.e. prior to the finalisation of the guidance document on how to utilize PPP dossiers for the preparation of BP dossiers.**

- **As a consequence, in many studies submitted by the applicant, the numbering system and format adopted under Directive 91/414/EEC and used for Plant Protection Products have been used. Several cross-references done by the applicant in the text of the studies, as well as in the text within justifications for non-submission of data, also refer to the dossier submitted under Directive 91/414/EEC (e.g., "PPP IIA 2.1.2/01"). A guide to the numbering system of 'BP vs. PPP' can be found in the last appendix of DOC I.**

- **In the reference list, however, the studies submitted are sorted also by reference number to facilitate the location of a study after its generic reference number (which is the same regardless of which directive it was submitted under).**

- **The CA's evaluations and in those cases where new study summaries have been submitted by the applicant, the numbering system of the TNsG on Preparation of Dossiers and Study Evaluation, adopted under Directive 98/8/EC, has been used.**

Section A6.1 Acute Toxicity

Annex Point IIA, VI.6.1

Section A6.1.1 Acute Oral Toxicity

Annex Point IIA, VI.6.1.1

Acute oral toxicity (Rat, IIA5.2.1/01, B01)

Report: Anon (1959)
The Acute Oral Toxicity of Vikane, Administration of Single Doses to Male Rats, Female Rats and Guinea Pigs
[redacted]
October 22, 1959. No report number

Guidelines: This study is pre-guideline
Deviations from EC guideline Method B.1. Acute Toxicity (Oral): There is not enough detail in this report to enumerate differences from guideline.

GLP: No – This study pre-dates GLP Compliance Programme

Methodology: Test material: Not specified in report available. The dosing solutions were prepared by bubbling the gas through chilled corn oil so that about 1% became Vikane to 99% oil. The volumes administered, of necessity, were very large--possibly leading to physiological effects.

Findings: Mortality was observed at 100 mg/kg bw and higher, as shown in Table 5.2.1/01-1.

Table 5.2.1/01-1: Single Dose Oral Toxicity of Vikane for Rats and Guinea Pigs

Species	Sex	Dose (mg/kg)	Mortality (No. Dying / No. Fed)	Observations
Rat	F	40	0/4	Nothing remarkable. Pathology very slight - possibly some in liver and lung
Rat	M	50	0/4	
Guinea Pig	F	50	0/4	
Rat	F	80	0/4	Oily diarrhea, dehydration. Slight liver and lung congestion, appreciable gastritis, and cloudy swelling in kidneys.
Rat	M	100	2/4	
Guinea Pig	F	100	2/4	
Rat	F	160	4/4	Deaths in a matter of hours. Mechanism not determined.
Rat	M	200	4/4	
Guinea Pig	F	200	4/4	
Rat	M	400	4/4	Death in 2 hours.
Guinea Pig	F	400	4/4	
Rat	F	40 cc of corn	0/2	No serious effects.

Species	Sex	Dose (mg/kg)	Mortality (No. Dying / No. Fed)	Observations
		oil		
Guinea Pig	F	40 cc of corn oil	2/4	All sick - recovery slow - oily diarrhea - loss of hair

Conclusions: **The LD_{50} for rats and guinea pigs is estimated at about 100 mg/kg bw.**

Section A.6.1.1 **Annex Point IIA, VI.6.1.1**	**Evaluation by Competent Authorities**
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	May 2004
Materials and Methods	The study is presented in a brief summary form only. There is no proper method description in the original report. The study was both pre-guideline and pre-GLP programme. The test material is not specified other than Vikane. To produce the dosing solutions the gas was bubbled through chilled corn oil to produce a 1 % solution. 4 animals/group were dosed (guinea pigs and rats of unknown strains and of different sexes). The doses were 0, 40, 50, 80, 100, 160, 200 and 400 mg/kg bw. All surviving animals were observed for two weeks.
Results and discussion	Study evaluation can not be performed properly due to the incomplete information provided. However, it gives some general idea on oral LC_{50} values. The LC_{50} for rats and guinea pigs is estimated at about 100 mg/kg bw. See table 5.2.1/01-1 for results. The volumes administered were very large, possibly leading to physiological effects.
Conclusion	The applicant's version is adopted.
Reliability	Reliability indicator 4: Unsuitable test system or conditions and/or insufficient reporting of methods and/or results data.
Acceptability	The study is acceptable only as information (see Remarks).
Remarks	Since sulfuryl fluoride is a gas an oral toxicity study is not required. However, this study gives some indications on the acute oral toxicity of this substance.

Section A6.1.2 Acute Percutaneous Toxicity

Annex Point IIA, VI.6.1.2

Acute percutaneous toxicity (Rat, IIA5.2.2/01, B07)

Report: [redacted] (1990)
Sulfuryl Fluoride: Four-Hour Dermal Vapor Exposure in Fischer 344 Rats
[redacted]
Report K-016399-036, -036A, -036B, dated 16/11/90; study began 20/2/90.

Guidelines: US EPA 81-5
Deviations from EC guideline Method B.3. Acute Toxicity (Dermal): There were no untreated control rats and the test material was a vapour.

GLP: Yes

Methodology: Test material: sulfuryl fluoride (Lot # 880329 752; 99.67% pure).
Groups of 5 Fischer 344 rats were exposed dermally to sulfuryl fluoride vapours of 987 ppm and 1013 ppm, respectively, for a single 4-hour period. Since no effects were noted from this exposure, another group of 5 F344 rats/sex was dermally exposed to 9599 ppm for a similar 4-hr period. This concentration (9599 ppm) was approximately 10-fold greater than the whole-body inhalation LC_{50} previously determined (B2/B3).
987 ppm = 4.145 mg/l
1013 ppm = 4.254 mg/l
9599 ppm = 40.315 mg/l
The dorsal skin on the rats was shaved with electric clippers prior to exposure to maximise effect. Surviving animals were weighed on days 1, 2, 4, 8, 11 and 15. Necropsy took place on day 15. The rats were observed during exposure and on test days 1 to 14 post-exposure. Sections of brain and skin were examined histologically. No other tissues were examined microscopically since no gross pathologic observations were noted.
Chamber concentrations were analysed using a Miran 1A infrared spectrophotometer and atmospheres were generated using a J-tube mixer with Saran bag delivering the test material. The chamber was 157 L Rochester-type. The chamber was modified in such a way that heads of the rats protruded through an elastic dental dam, which served as a barrier between the test material and the breathing air for the rats. The breathing air contained <20 ppm SO_2F_2.

Findings: All animals survived the 4-hour exposure and 14 day post-exposure period with no clinically visible effects. In all exposure groups, the average body weight on day 2 was decreased slightly (3%) from pre-exposure values, as shown in Table 5.2.2/01-1. This was thought to be due to the stress of handling and restraint, rather than due to sulfuryl fluoride exposure. By day 4, body weight values were greater than pre-exposure values, and these animals continued to gain weight. There were no grossly visible lesions noted in animals necropsied at the end of the 14-day post-exposure period. Histopathologic examinations of brain and skin samples taken from animals exposed to 9599 ppm revealed no treatment-related effects.

Table 5.2.2/01-1 Mean Body Weights after Single Dermal Exposure

Dose (ppm)	Days on Test					
Males	**1**	**2**	**4**	**8**	**11**	**15**
987	110.9	109.7	115.3	141.7	157.1	178.1
9599	124.4	121.1	137.7	160.3	174.8	193.7
Females	**1**	**2**	**4**	**8**	**11**	**15**
1013	118.0	117.0	119.4	125.6	133.3	137.6
9599	92.9	90.2	98.1	108.0	114.5	120.8

Conclusions: **Results of this study indicate no acute toxicological hazard on exposure to sulfuryl fluoride via the skin.**

Section A 6.1.2 **Annex Point AII, VI.6.1.2**	**Evaluation by Competent Authorities**
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	May 2004
Materials and methods	The applicant's version is adopted with a minor revision about deviations from the guideline. Deviations from EC guideline method B3: The test material was a gas. No LC_{50} value was calculated. However, dermal toxicity studies are not required for gases according to the TNsG for Data Requirement. Clarification: There were 5 rats/sex/group.
Results and discussion	The applicant's version is adopted.
Conclusion	Based on the results of this study sulfuryl fluoride gas does not appear to represent an acute toxicological hazard after dermal exposure of concentrations up to 9599 ppm (40.36 mg/L).
Reliability	Reliability indicator 1: Study conducted in compliance with agreed protocols, with no or minor deviations from standard test guidelines and/or minor methodological deficiencies, which do not affect the quality of relevant results.
Acceptability	The study is acceptable.
Remarks	Exposure to sulfuryl fluoride via inhalation was <20 ppm under the experimental conditions.

Section A6.1.3/01 **Acute Inhalation Toxicity**

Annex Point IIA, VI.6.1.3

Acute inhalation toxicity (Rat, IIA/5.2.3/01, B02)

Report: Anon. (1959)
The Acute Vapor Toxicity of Vikane as Determined on Male and Female Rats, Single Exposures of Groups of Rats to High Concentrations of Vikane in Air
[redacted]
October 22, 1959. No report number

Guidelines: This study is pre-guideline.
Deviations from EC guideline Method B.2. Acute Toxicity (Inhalation): This study used more animals than the guideline, more concentrations than required, more times of exposure, no body weights reported, but the report is too sketchy to determine full comparison. However, this study has enough data to be able to rely on the data.

GLP: No – this study pre-dates the GLP Compliance Programme

Methodology: Test material: Not specified
Single exposures to Vikane were conducted in a 160 L glass and 'Monel' chamber using groups of 8-20 rats of each sex. The concentration of Vikane was maintained by pumping the gas from a Saran bag by means of a Dual Syringe Feeder Pump. The air flow through the chamber was continuous and ranged from 4-19 L/minute.
The concentrations during part of the exposures were monitored by means of a Recording IR with a 4.5 m cell. The concentrations were within 10% of the calculated levels. During the exposures of male rats to 1000 ppm, the chamber atmosphere was analysed for Vikane by taking grab samples, hydrolysing the fluoride with caustic and determining the liberated fluoride by a Thorium-Alizarin method. The amount of fluoride recorded agreed closely with the theoretical value for 1000 ppm of SO_2F_2.

Findings: Findings are summarised below in Table 5.2.3/01.

Table 5.2.3/01: Summary of Exposure of Rats to Vikane

Conc. (ppm)	lbs/1000 ft^2	Exposure Duration (hours)	Sex	No. Died/ No. Exposued	Response - Remarks
15,000	**3.9**	0.2	M	18/18	Very quiet during the last half exposure. Drowsy and laboured breathing when removed. Tremors shortly after removal. Convulsing about 48 minutes after exposure. Convulsions similar to strychnine - all dead after 3 hours.
			F	9/10	
15,000	**3.9**	0.1	M	1/18	Very little response during exposure. Slow moving on removal. Two hours after exposure one rat started convulsing and subsequently died.
			F	0/10	