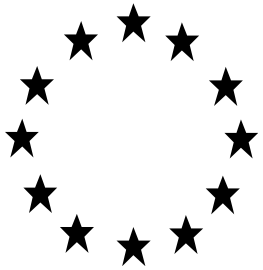
Directive 98/8/EC concerning the placing biocidal products on the market

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

Assessment Report



SULFURYL FLUORIDE

PT8

September 2006

Assessment report for the active substance

Sulfuryl fluoride (PT8)

Finalised in the Standing Committee on Biocidal Products at its meeting on 8 September 2006 in view of its inclusion in Annex I to Directive 98/8/EC

1. Procedure followed

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

Sulfuryl fluoride (CAS no. 2699-79-8) was notified as an existing active substance, by Dow AgroSciences GmbH, Truderinger Strasse 15, 81677 Muenchen, Germany in Product Type 8 (wood preservative) and 18 (insecticide) for professional use only.

Commission Regulation (EC) No 2032/2003 of 4 November 2003[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 10 of that Regulation, the Commission designated Sweden as Rapporteur Member State to carry out the assessment of sulfuryl fluoride on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for sulfuryl fluoride as an active substance in Product Type (PT) 8 was 28 March 2004, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 29 January 2004, Dow AgroSciences submitted a dossier to the Swedish competent authority. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation, taking into account the supported uses, and confirmed the acceptance of the dossier on 28 April 2004. In May 2004, in accordance with Article 9(3) of Regulation 2032/2003 Dow AgroSciences sent the summary dossier to the Commission and the Member States.

On 19 April 2005, Sweden submitted, in accordance with the provisions of Article 11(2) of Directive 98/8/EC and Article 10(5) of Regulation 2032/2003, to the Commission and Dow AgroSciences a copy of the evaluation, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 27 April 2005. The competent authority report included a recommendation for the inclusion of sulfuryl fluoride in Annex I to the Directive for PT 8.

[1] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market, OJ L 123, 24.4.98, p.1
[2] OJ L 307, 24.11.2003, p. 1

In accordance with Article 12 of Regulation (EC) 2032/2003, the Commission made the competent authority report publicly available by electronic means on 26 May 2005. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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

On the basis of the final competent authority report, the Commission proposed the inclusion of sulfuryl fluoride in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 8 September 2006.

The present assessement report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 8 September 2006. This assessment report should be read in conjunction with Documents I and II of the competent authority report, including in particular the summary referred to in Section X of Annex IIA and IIB to Directive 98/8/EC.

2. Purpose of the assessement report

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

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

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

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

The overall conclusion from the evaluation is that it may be expected that wood preservatives containing sulfuryl fluoride will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is however subject to:

i) compliance with the particular requirements in sections 4, 5, 6 and 7 of this assessment report,
ii) the implementation of the provisions of Article 5(1), and
iii) the common principles laid down in Annex VI to Directive 98/8/EC, for each wood preservative containing sulfuryl fluoride.

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

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the applicant (see Appendix III to this assessement report).

Extension of the use pattern beyond those described in Appendix III will require an evaluation at Member State level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI of Directive 98/8/EC.

The following reference values have been established:

AOEC bystander: 3 ppm[4]

AOEC operator: 1 ppm[5]

Operator exposure limit value: 3 ppm

The AOEC values for operators and bystanders respectively, have been proposed as results of the toxicological risk assessment. The AOEC of 1 ppm for operators should be regarded as the concentration of sulfuryl fluoride in air that workers could be exposed to constantly for a full working day over a longer period of time. The operator exposure limit value of 3 ppm represents the air concentration for sulfuryl fluoride when workers should use personal protective equipment (PPE), in the form of self-contained breathing apparatus (SCBA).

As provided for in Article 5(1) (b) (iii) and (iv) of Directive 98/8/EC, the review has also concluded that under the proposed and supported conditions of use, no unacceptable effects on the environment have been identified.

4. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of sulfuryl fluoride are given in Appendix I.

The competent authority report has established that, on the basis of information currently available for sulfuryl fluoride notified by the Dow AgroSciences, none of the manufacturing impurities considered are of toxicological or environmental concern.

5. Endpoints and related information

In order to facilitate Member States in granting or reviewing authorisations, to apply adequately the provisions of Article 5 of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints were identified during the evaluation process. These endpoints are listed in Appendix II of this summary.

6. Particular conditions to be taken into account by Member States in relation to the granting of authorisations of biocidal products containing sulfuryl fluoride

On the basis of the proposed and supported uses (as listed in Appendix III), the following issues have been identified as requiring particular attention from all Member States, in the framework of any authorisations to be granted, modified or withdrawn, as appropriate:

[4] Based on short-term exposure
[5] Based on long-term exposure

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

(1) the product may only be sold to and use by professionals trained to use it;

(2) appropriate risk mitigation measures are included for operators and bystanders;

(3) concentrations of sulfuryl fluoride in remote tropospheric air are monitored.

Member States shall also ensure that reports of the monitoring referred to in point (3) are transmitted by marketing authorisation holders directly to the Commission every fifth year starting from 1 January 2009.

Member States shall pay particular attention to the criteria in Article 5(1) (b) of Directive 98/8/EC and shall ensure that any necessary data and information is provided before such authorisations are granted.

7. List of studies to be generated

No further studies were considered necessary in relation to the inclusion of sulfuryl fluoride, in Annex I to Directive 98/8/EC for PT 8.

8. Information on studies with claimed data protection

Appendix IV gives information about the studies for which data protection is claimed and which during the evaluation process were considered for the purpose of Annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 8 of Directive 98/8/EC in the Member States. It is based on the best information available at the time this assessement report was prepared; but it does not prejudice any rights or obligations of Member States, the Commission or operators with regard to its uses in the implementation of the provisions of Article 8 of the Directive 98/8/EC.

9. Updating of this assessement report

In order to take account of technical and scientific developments, the inclusion of sulfuryl fluoride may be reviewed at any time if there are indications that any of the requirements referred to in the inclusion directive and Article 10(1) of Directive 98/8/EC are no longer satisfied.

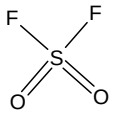
Likewise, in accordance with article 11(5) of Regulation 2032/2003, should a Member State receive new information on sulfuryl fluoride, in particular during the product authorisation process, it shall, where necessary, propose an amendment to the assessment report. Such proposal shall be reviewed by the Member States and the Commission within the Standing Committee on Biocidal Products. Where appropriate, the assessment report shall be updated and the conditions of inclusion of the substance in Annex I to Directive 98/8/EC shall be amended in accordance with Article 10(4) of Directive 98/8/EC.

APPENDIX I

Identity, Physical and Chemical Properties

SULFURYL FLUORIDE

Identity

Chemical name (IUPAC)	Sulfuryl difluoride/Sulfuryl fluoride
Chemical name (CA)	Sulfuryl fluoride
CAS No	2699-79-8
EC No	220-281-5
Other substance No.	Not allocated
Minimum purity of the active substance as manufactured	994 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured	There are no relevant impurities in the active substance as manufactured.
Molecular formula	SO_2F_2
Molecular mass	102.1 g/mol
Structural formula	

Physical and chemical properties

Melting point	-136.8 °C (purity 99.4 mol%)
Boiling point	-54°C ± 1 °C (purity 98.8 %)
Temperature of decomposition	Not required. No decomposition or sublimation occurs at the melting or boiling temperature. It is a gas. According to theoretical assessment the gas itself is considered to be thermally stable up to 1227 °C.
Appearance	Colorless gas (purity 98.8%). Odour not determined due to hazardous nature of test substance.
Relative density	4.2 g/l at 20 °C and 1 atm, calculated from the Ideal Gas Law
Surface tension	67.5 mN/m (90% saturated solution) (purity 99.8%) at 20 °C
Vapour pressure	1.6 MPa at 20 °C (purity 99.35-99.51 mol %)
Henry's law constant	Not required for substances which are gases. Calculated for other purposes as: 158142 Pa m^3 mol^{-1} (1.56 atm m^3 mol^{-1})

Solubility in water	In unbuffered water (pH=2.5): 1.04 g/l at 20 °C (purity 99.8%)
Solubility in organic solvents	Solvent — Solubility g/l (20 °C) n-heptane 22 xylene 25 1,2-dichloroethane 25 methanol 33 acetone 71 ethyl acetate 59 n-octanol 14
Stability in organic solvents used in biocidal products including relevant breakdown products	Not relevant. The active ingredient is the product.
Partition coefficient (log P_{OW})	In unbuffered solutions: Log P_{ow} = 0.14, measured at 20 °C
Hydrolytic stability (DT_{50})	(purity >99%) pH 2, 25 °C: 5.3 days pH 5.9, 25 °C: 3.1 days pH 7, 20 °C: 6.7 hours pH 7, 25 °C: 4.6 hours pH 9, 20 °C: 4.0 min pH 9, 25 °C: 2.8 min
Dissociation constant	Not required - test substance does not reversibly ionize
UV/VIS absorption (max.)	<u>In purified water (pH=2.0)</u> λ (nm) ε (L x mol^{-1} x cm^{-1}) 276 37 <u>In 0.1 M HCl (pH=1.3)</u> λ (nm) ε (L x mol^{-1} x cm^{-1}) 278 61 No absorption maxima >290 nm
Photostability (DT_{50})	Not determined (in water) due to high vapour pressure
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not determined (in water) due to high vapour pressure
Flammability	Non-flammable and not considered to be auto-flammable
Explosive properties	Not explosive

APPENDIX II

End Points and Related Information

SULFURYL FLUORIDE

Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

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

Acute toxicity

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

Repeated dose toxicity

Species/ target/critical effect	Rat: irritation in respiratory tract, alveolar histiocytosis, mild hyperplasia in kidney, vacuolation in cerebrum. Dog: irritation in respiratory tract and aggregates of macrophages in alveoli, microscopic dental fluorosis. At higher doses (200 ppm), minimal vacuolation and gliosis of the brain. Rabbit: irritation in respiratory tract, vacuolation in cerebrum. Mouse: vacuolation in cerebrum.
Lowest relevant oral NOAEL/LOAEL	No reliable data
Lowest relevant dermal NOAEL/LOAEL	Not applicable.
Lowest relevant inhalation NOAEL/LOAEL	30/100 ppm (mouse) 20/80 ppm (dog, 20 ppm based on local effect and microscopic dental fluorosis that is not considered relevant in this case; 12-month)

Genotoxicity	No genotoxic risk to humans

Long term toxicity

Species/target/critical effect	Rats: chronic progressive glomerular nephrosis and minor lung irritation (2 year study). Mice: very slight vacuolation in cerebrum exacerbation of systemic amyloidosis in females (18 month study).
Lowest relevant NOAEL/LOAEL	20/80 ppm (rat and mouse) NOEL: 5 ppm based on dental fluorosis (rat). This is considered an adverse effect that is not relevant in this case.

Carcinogenicity

Species/type of tumour	Non-carcinogenic in rat or mouse
Lowest dose with tumours	No tumours observed

Reproductive toxicity

Species/reproduction target/critical effect	Rat. Reproduction: none Parental: aggregates of alveolar macrophages at 20 ppm Offspring: ↓ bodyweight gain at 150 ppm
Lowest relevant NOAEL	Reproduction: 150 ppm (highest dose tested) Parental: 5 ppm (based on a local effect)

	Offspring: 20 ppm
Species/developmental target / critical effect	Not teratogenic in rat or rabbit. Rabbit: reduced body weight in dams and offspring at 225 ppm.
Lowest relevant NOAEL	Developmental: 75 ppm (rabbit) Maternal: 75 ppm (rabbit)

Neurotoxicity / Delayed neurotoxicity

2-day acute neurotoxicity study in rats	No evoked potentials affected. The NOEL was 300 ppm (highest dose tested).
13-weeks neurotoxicity study in rats	Slowing of visual, auditory and somatosensory evoked potentials Mild vacuolation of the brain at 100 ppm NOEL: 30 ppm.
12-month chronic neurotoxicity study in rats	No neurotoxic effects at the highest dose. NOEL: 80 ppm

Medical data

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

Summary	Value	Study	Safety factor
ADI (if residues in food or feed)	Not relevant	-	-
AOEC (Operator/Worker)	1 ppm[#]	Mouse 90 day inhalation study	100
AOEC (Bystander)	3 ppm[*]	Rat acute neurotoxicity	100
Drinking water limit	Not relevant	-	-
ARfD (acute reference dose)	Not relevant	-	-

[#] Based on long-term exposure
[*] Based on short-term exposure

Acceptable exposure scenarios (including method of calculation)

Professional users	Based on the data from structural fumigation trials. Acceptable exposure provided fumigators wearing respiratory protective equipment (self-contained breathing apparatus) when introducing and aerating the gas or in any occasion that air concentration of the gas is above 3 ppm. Under these conditions the

	long term exposure will not exceed the AOEC of 1 ppm.
Workers (re-entry)	Based on the data from structural fumigation trials. Re-entry for non-fumigation workers is not allowed until the air concentrations of sulfuryl fluoride have been measured and confirmed by the fumigator to be below a limit value of 3 ppm.
Non-professional users	Not applicable.
Indirect exposure as a result of use	Bystanders (general population) are relevant only to structural fumigations. Appropriate measures to protect bystanders during fumigation and venting of treated buildings or other enclosures must be taken. The exposure level of sulfuryl fluoride in air shall not exceed 3 ppm.

Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50})	pH 2, 25 °C: 5.3 days pH 5.9, 25 °C: 3.1 days pH 7, 25 °C: 4.6 hours (20 °C: 6.7 hours) pH 9, 25 °C: 2.8 min (20 °C: 4.0 min)
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Not applicable.
Readily biodegradable	Not applicable.
Biodegradation in seawater	Not applicable.
Non-extractable residues	Not applicable.
Distribution in water / sediment systems (active substance)	Not applicable.
Distribution in water / sediment systems (metabolites)	Not applicable.

Route and rate of degradation in soil

Mineralization (aerobic)	Not applicable.
Laboratory studies	Not applicable.
Field studies	Not applicable.
Anaerobic degradation	Not applicable.
Soil photolysis	Not applicable.
Non-extractable residues	Not applicable.
Relevant metabolites - name and/or code, % of applied a.i.	Not applicable.
Soil accumulation and plateau concentration	Not applicable.

Adsorption/desorption

Ka, Kd Ka_{oc}, Kd_{oc} pH dependence	K_{OC} 0.566 l/kg (theoretical estimate of the organic carbon-water partitioning)

Fate and behaviour in air

Direct photolysis in air	T½ (estimated): >2 years at the surface of the earth T½ (estimated): >1.1 years at the top of the troposphere

Quantum yield of direct photolysis	Not determined (assumed as 1 in above estimate)
Photo-oxidative degradation in air	*k (rate constant)* = $<<10^{-12}$ cm^3/molecule sec
Volatilization	Not applicable; permanent gas

Monitoring data, if available

Soil	None
Surface water	None
Ground water	None
Air	Local scenario: Monitoring of air concentrations at various positions around mills during fumigation and venting processes (trials) has yielded maximum 24-hour time weighted average concentrations for a range of distances from the mill. The 90^{th} percentile of 1.51 ppm (6.3 mg/m^3) at 5 metres was taken to represent the "worst-case" scenario of maximum exposure for any individuals in the vicinity of the mill. Global scenario: Sulfuryl fluoride has not been identified in remote air samples at an LOD of 0.5 ppt (2.1 ng/m^3).

Effects on Non-target Species

Toxicity data for aquatic species

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

Effects on earthworms or other soil non-target organisms

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

Effects on soil micro-organisms

Nitrogen mineralization	Not applicable.
Carbon mineralization	Not applicable.

Effects on terrestrial vertebrates

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

Effects on honeybees

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

Effects on other beneficial arthropods

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

Bioconcentration

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

APPENDIX III

List of Uses Supported by Available Data

SULFURYL FLUORIDE

Object and/or situation

Disinfestation of wood from wood destroying pests. Uses include structures/rooms (e.g. churches, houses), wooden objects and timber in fumigation chambers, shipment containers and in stacks under tarpaulins

Member State or Country

Sweden, Germany

Product name

Vikane (The trade name 'ProFume' is also used for PT18 under Directive 98/8/EC and for applications under Directive 91/414/EEC. Vikane and ProFume are identical products.)

Organisms controlled

- Dry wood termites (*Cryptotermes cavifrons*, *Incisitermes minor*, *Incisitermes snyderi*, *Neotermes jouteli*, *Kalotermes approximates).*
- Formosan termites *(Coptotermes formosanus*).
- Wood infesting beetles *(Anobium punctatum, Lyctus brunneus, Hylotrupes bajulus*).
- Pinewood nematode *(Bursaphelenchus xylophilus).*

Formulation

Type: Gas

Concentration of a.s.: 99.8 g/kg (typical value). Min. purity: 99.4 g/kg

Application

Method, kind: Fumigation

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

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

Applied amount per treatment

Gram as/l, min – max: not applicable

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

Dosage, min – max: The dosage required for effective control is derived from the product (P) of fumigant concentration (C) x time (T), referred to as the CTP. The CTP is given in g-h/m^3 (gram hours per cubic metre). The maximum concentration is 128 g/m^3 with no restriction for exposure time. The CTP required is dependent on the pest species, the life stage and the temperature. Dosages are determined by the use of Fumiguide calculator which takes into account these factors. To simplify the use of the calculator the dosage is provided for a single pest; dry wood termites. Dosages for other pests are then calculated as a multiple of this value. For example for a 48 hour fumigation of a structure undertaken at 25 °C with a half loss time of 12 hours (time taken for 50% of the fumigant to be lost) the dosages (in g-h/m^3) are as follows:

Dry wood termites		x = 78
Formosan termites		4X = 312
Lyctus brunneus	Non-egg stage	4X = 312
	Egg stage	15X = 1170
Anobium punctatum	Non-egg stage	4X = 312
	Egg stage	20X = 1560
Hylotrupes bajulus	Non-egg stage	4X = 312
	Egg stage	20X = 1560
Pinewood nematode	All stages	20X = 1560

Remarks

If fumigating for insect pests, do not apply when temperature at the site of the pest activity is below 10 °C. This temperature may be measured at the slab foundation, sub-floor or wherever the coolest part of the fumigation site may be. For pinewood nematode; do not apply at temperatures below 20 °C.

APPENDIX IV

List of Studies

SULFURYL FLUORIDE

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

Identity

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
Ammons, R.W.	Vikane Product Release, Lot number 874	The Dow Chemical Company	N	N	N	Y (ii)	D	K-016399-037	February 1990

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
Anon	Vikane Analysis – K-16399-018	The Dow Chemical Company, Midland, Mi, USA	N	N	N	Y (ii)	D	K-16399-018	April 1980
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
Campbell, R.A.	Composition Report, Vikane UDS Assay	The Dow Chemical Company	N	N	N	Y (ii)	D	GT-45-91	May 1991
Ghaoui, L.H.	Group A: Product Identity and Composition, Description of Materials used to Product the Product, Description of the Production Process, Discussion of Formation of Impurities, Certified Limits, Preliminary Analysis, and Enforcement Analytical Methods for Sulfuryl Fluoride Technical	Formulation Science and Technology, Dow AgroSciences, Indianapolis	N	N	N	Y (ii)	D	NAFST361	January 2001
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
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
Langvardt, P.	Analytical Data Sheet 88-226, Vikane Inhalation	The Dow Chemical Company	N	N	N	Y (ii)	D	88-226	October 1988

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
Markham, D.A.	Chemical Purity, Analytical Report Number: 91-232. Vikane 18 month inhalation CD-1 mice and Vikane Reproduction	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	91-232	November 1991
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
Markham, D.A.	Chemical Purity, Analytical Report Number: 91-194.Vikane 18 month inhalation CD-1 mice	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	91-194	October 1991
Markham, D.A.	Chemical Purity, Analytical Report Number: 91-100. Vikane 18 month inhalation CD-1 mice.	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	91-100	May 1991
Markham, D.A.	Chemical Purity, Analytical Report Number: 93-54, Vikane 18 months mouse, 2-year rat and 1 year dog chronic inhalation studies	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	93-54	February 1993
Markham, D.A.	Chemical Purity, Analytical Report Number: 92-45, Vikane chronic/onco. Rat& mouse inhalation and Vikane 1-year chronic dogs	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	92-45	March 1992

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
Markham, D.A.	Chemical Purity, Analytical Report Number: 92-163. Vikane 18 month mouse, 2-year rat and 1-year dog chronic inhalation studies	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	92-163	July 1992
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
Roll, H.	Vikane Product Release, Lot Number 141	The Dow Chemical Company	N	N	N	Y (ii)	D	HET-K-16399-13	March 1979
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
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

Physical and Chemical Properties

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
Anon	Sulfuryl Fluoride, Temperature Dependent Properties, PPDS System DataBank	The Dow Chemical Company, USA	N	N	N	Y (ii)	D	PPDS 2790	July 2002
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
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
Ghaoui, L.H., Thornburgh S.	Nuclear Magnetic Resonance Study for Sulfuryl Fluoride	Dow AgroSciences, Indianapolis	N	N	N	Y (ii)	D	FOR00006	August 2000
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
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
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
Russell, M.W	Determination of the purity and identity of Sulfuryl Fluoride, TSN101693	Dow AgroSciences	Y	N	N	Y (ii)	D	NAFST244	May 2000

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
Russell, M.W.	Stability of Sulfuryl Fluoride	Dow AgroSciences, Indianapolis, USA	Y	N	N	Y (ii)	D	NAFST383	August 2001

Analytical Methods

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
Barnekow, D.E., Foster, D.R.	Interim Report – Storage Stability of Sulfuryl Fluoride on SKC 1 g Anasorb CSC Tubes at Ambient and Frozen Temperature Conditions	Regulatory Laboratories-Indianapolis Lab, Dow AgroSciences, Indiana, USA	Y	N	N	Y (ii)	D	990040.01	June 2002
Barnekow, D.W., Byrne, S.L., Foster, D.R.	Determination of Exposure Potential to Workers and Atmospheric Concentrations of Sulfuryl Fluoride During and Following Fumigation of Mills Using ProFume – North America 2002	Paragon Research Services, Fresno, CA, USA and MVTL Laboratories, New Ulm, MN, USA and Reg. Laboratories-Indianapolis Lab, Dow AgroSciences LLC, Indianapolis, IN, USA	Y	N	N	Y (ii)	D	020039	June2002
Blaschke, U.	Sulfuryl Fluoride, Determination of Atmospheric Concentrations of Sulfuryl Fluoride and Occupational Exposure of Fumigators during the structural Fumigation of a Mill using ProFume Germany 2002	Huntingdon Life Sciences, Ltd, Huntingdon, UK	Y	N	N	Y (ii)	D	DOS 299/023404	July 2002
Hall, L.L., Smith, F.A., De Lopez, O.H., Garner, D.E.	Direct Potentiometric Determination of Total Ionic Fluoride in Biological Fluids.	Clinical Chemistry, 18/12, 1455-1458 (1972)	N	Y	N	N	P	None	1972
Huff, D.W; Murphy, P.G	Sulfuryl Fluoride: Re-validation of air monitoring method HEH2.12-38-26(6)	DowElanco, Indianapolis	N	N	N	Y (i)	D	HEH 174	November 1995

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
Jones, G.E., Perkins, J.M.	Determination of Atmospheric Concentration of Sulfuryl Fluoride Following Fumigation of a Mill using ProFume – UK 2002	Agrisearch Uk Ltd, Melbourne, UK and Minnesota Valley Testing Laboratories, New Ulm, MN, USA	Y	N	N	Y (ii)	D	AF/6268/DE	July 2002
Kissa, E.	Determination of Inorganic Fluoride in Blood with a Fluoride Ion-Selective Electrode.	Clinical Chemistry, 33/2, 253-255 (1987)	N	Y	N	N	P	None	1987
Murphy, P.G., Contardi, J.S.	Sulfuryl Fluoride: Development and Validation of an Air Monitoring Method	DowElanco	N	N	N	Y (i)	D	HEH2.12-38-26(6)	July 1994
Stolz, W.L.,	Analytical Method for the Determination of Vikane* Gas Fumigant: Validation Report	Dow U.S.A. Western R& D Pittsburg	N	N	N	Y (i)	D	FOR92080.01	March 1993
Stolz, W.L., Fields S.M.	Analytical Method for the Determination of Selected Impurities in Vikane* Gas Fumigant: Validation Report	Dow U.S.A. Western R& D Pittsburg	N	N	N	Y (i)	D	FOR92080.02	March 1993

Effectiveness Against Target Organisms and Intended Uses

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
Binker, G., Binker, J., Fröba, G. and Franke, P.	Laboratory study on *Anobium punctatum* Number: 121.08.1998 No.1. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	37	1998
Binker, G., Binker, J., Fröba, G. and Franke, P.	Laboratory study on *Anobium punctatum* Number: 121.08.1998 No.2. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	38	1998
Binker, G., Binker, J., Fröba, G. and Franke, P.	Laboratory study on *Anobium punctatum* Number: 121.08.1998 No.3. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	39	1998
Binker, G., Binker, J., Fröba, G. and Franke, P.	Laboratory study on *Anobium punctatum* Number: 121.08.1998 No.4. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	40	1998
Binker, G., Binker, J., Fröba, G. and Franke, P.	Field study on *Anobium punctatum* Number: 111.05.1997. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	41	1997
Binker, G., Binker, J., Fröba, G., Franke, P. and Ultsch, R.	Field study on *Anobium punctatum* Number: LBM 541 1320/113. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	31	2001

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
Binker, G., Binker, J., Fröba, G., Franke, P. and Ultsch, R.	Field study on *Anobium punctatum* Number: LBM 541 1320/116. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	32	2001
Binker, G., Binker, J., Fröba, G., Franke, P. and Ultsch, R.	Field study on *Anobium punctatum* Number: MBP 548 1317/20. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	33	2001
Binker, G., Binker, J., Fröba, G., Franke, P. and Ultsch, R.	Field study on *Anobium punctatum* Number: MBP 548 1317/32. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	34	2001
Binker, G., Binker, J., Fröba, G., Franke, P. and Ultsch, R.	Field study on *Anobium punctatum* Number: LBM 540 1336/30. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	35	2000
Binker, G., Binker, J., Fröba, G., Franke, P. and Ultsch, R.	Field study on *Anobium punctatum* Number: LBM 540 1336/37. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	36	2000
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 121641. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	11	1995
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Field study on *Anobium punctatum* Number: 123418/B and 123418/D. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	12	1996

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
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Field study on *Anobium punctatum* Number: 123418/C and 123418/D. Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	13	1996
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 125749/C and 125749/E (Bioassay 151 – 160). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	14	1997
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 125749/C and 125749/E (Bioassay 161 - 180). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	15	1997
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 125749/C and 125749/E (Bioassay 181 – 200). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	16	1997
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Field study on *Anobium punctatum* Number: 402741/A and 402741/B (Bioassay 1 – 60). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	17	2000

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
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Field study on *Anobium punctatum* Number: 402741/A and 402741/B (Bioassay 61 - 120). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	18	2000
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 402741/C and 402741/D (Bioassay 143 - 165). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	19	2000
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 402741/C and 402741/D (Bioassay 166 - 188). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	20	2000
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 130377/A and 403972 (Bioassay 11 – 15). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	21	1999
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 130377/A and 403972 (Bioassay 16 - 20). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	22	1999

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
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 130377/A and 403972 (Bioassay 21 - 25). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	23	1999
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 130377/A and 403972 (Bioassay 26 - 30). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	24	1999
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 130377/A and 403972 (Bioassay 31 - 35). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	25	1999
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 130377/A and 403972 (Bioassay 36 - 40). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	26	1999
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 130377/A and 403972 (Bioassay 41 - 45). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	27	1999

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
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 130377/A and 403972 (Bioassay 46 - 50). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	28	1999
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 130377/A and 403972 (Bioassay 51 - 55). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	29	1999
Binker, G., Binker, J., Fröba, G., Graf, E., and Lanz, B.	Laboratory study on *Anobium punctatum* Number: 130377/A and 403972 (Bioassay 56 - 60). Unpublished.	Binker Materialschutz, Germany	Y	N	N	Y (ii)	D	30	1999
Ducom, P., Roussel, C., and Stefanini, V.	Efficacy of sulfuryl fluoride on European house borer eggs, Hylotrupes bajulus (L.) (Coleoptera; Cerambycidae).	Laboratoire National de la Protection des Végétaux, Station d`Etude des Techniques de fumigation et de Protection des Denrées Stockées, Chemin d`Artigues -33150 Cenon, France.	Y	N	N	Y (ii)	D	08	2003
Dwinell, L.D., Thoms, E., and Prabhakaran, S.	Exploratory research on sulfuryl fluoride fumigation to eradicate the pine wood nematode in unseasoned pine lumber.	Annual Inter-national Research Conference on Methyl Bromide Alternatives and Emission Reduction, 2003, San Diego, California, USA.	N	Y	N	N	P	06	2003

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
La Fage, J.P., Jones, M., and Lawrence, T	A laboratory evaluation of the fumigant, sulfuryl fluoride (Vikane), against the Formosan termite *Coptotermes formosanus* Shiraki.	Publication: The International Research Group on Wood Preservation, Thirteenth Annual Meeting, May 1982. IRG Secretariat Drottning Kristinas väg 47C, S – 11428 Stockholm, Sweden.	N	Y	N	N	P	04	1982
Osbrink, W.L.A., Scheffrahn, R.H., Su, N-Y., and Rust, M.K.	Laboratory comparisons of sulfuryl fluoride toxicity and mean time of mortality among ten termite species (Isoptera: Hodotermitidae, Kalotermitidae, Rhinotermitidae).	Publication: Journal of Economic Entomology Volume 80, pages 1044 – 1047.	N	Y	N	N	P	01	1987
Prabhakaran, S.K. and Ray, S.	ProFume Resistance Risk Analysis (Sequential Quantitative Resistance Model)	Dow AgroSciences, Mooresville, USA	N	N	N	Y (ii)	D	None	December 2002
Soma, Y., Naito, H., Misumi, T., Mizobuchi, m., Tsuchiya, Y., Matsuoka, I., Kawakami, F., Hirata, K., and Komatsu., H.	Effects of some fumigants on pine wood nematode, *Buraphelenchus xylophilus*, infecting wooden packages. Susceptibility of pine wood nematode to methyl bromide, sulfuryl fluoride and methyl isothiocyanate.	Publication: Research Bulletin Plant Protection, Japan, 2001, Number 37, pages 19 – 26.	N	Y	N	N	P	05	2001

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
Su, N-Y., and Scheffrahn, R.H.	Field comparison of sulfuryl fluoride susceptibility among three termite species (Isoptera: Kalotermitidae, Rhinotermitidae) during structural fumigation.	Publication: Journal of Economic Entomology Volume 79, pages 903 – 908.	N	Y	N	N	P	03	1986
Su, N-y., and Scheffrahn, R.H.	Efficacy of sulfuryl fluoride against four beetle pests of museums (Coleoptera: Dermestidae, Anobiidae).	Publication: Journal of Economic Entomology Volume 83, pages 879 – 882.	N	Y	N	N	P	09	1990
Su, N-Y., Osbrink, W.L.A., and Scheffrahn, R.H.	Concentration-time relationship for fumigant efficacy of sulfuryl fluoride against the Formosan subterranean termite (Isoptera: Rhinotermitidae).	Publication: Journal of Economic Entomology Volume 82, pages 156 – 158.	N	Y	N	N	P	02	1989
Verheyen, H.	Investigatory studies on the ovicidal effect of a fumigant on dry wood insect pests.	Fachhochschule, Eberswalde, Germany. Student Research Project	Y	N	N	Y (ii)	D	07	2002
Williams, L.H., and Sprenkel, R.J.	Ovicidal activity of sulfuryl fluoride to Anobiid and Lyctid beetle eggs of various ages.	Publication: Journal of Entomological Science, Vol. 25(3), pages 366 – 375.	N	Y	N	N	P	10	1990

Toxicological and Metabolic Studies

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
Albee, R. R., Eisenbrandt, D. L Mattisson, J. L. Streeter, C. M.	Sulfuryl Fluoride (Vikane*) Induced Incapacitation In Rats	Dow Chemical Company, Midland	Y	N	Y	Y (ii)	D	K-016399-018	September 1983
Albee, R.R., Spencer, P.J, Bradley, G.J.	Sulfuryl Fluoride: Electrodiagnostic, FOB and Motor Activity Evaluation of Nervous System Effects from Short-term Exposure	Toxicology Research Laboratory, The Dow Chemical Company, Midland, USA	Y	N	Y	Y (i)	D	K-016399-045	May 1993
Anon	The Acute Oral Toxicity to Vikane Administration of Single Doses to Male Rats, Female Rats and Guinea Pigs	Dow Chemical Company, Midland	N	N	Y	Y (ii)	D	None	October 1959
Anon	The Acute Vapor Toxicity Of Vikane As determined on Male and Female Rats	Dow Chemical Company, Midland	N	N	Y	Y (ii)	D	None	October 1959
Anon	Short Term Dietary Feeding Study of Commercial Laboratory Diet Fumigated with Vikane	Dow Chemical Company, Midland	N	N	Y	Y (ii)	D	None	October 1959
Anon	The Chronic Vapor Toxicity of Vikane as Determined on Laboratory Animals	Dow Chemical	N	N	Y	Y (ii)	D	None	October 1959
Barnekow, D.E, Byrne, S.L. Foster, D.R.	Sulfuryl Fluoride Exposure Potential to Workers Involved in the Fumigation and Aeration of Mills Using ProFume – North America	Global Environmental Chemistry Laboratory, Dow AgroSciences , Indianapolis, Indiana, USA	Y	N	N	Y (ii)	D	010052	March 2002

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
Barnekow, D.E., Byrne, S.L., Foster, D.R.	Determination of Atmospheric Concentrations of Sulfuryl Fluoride Following Fumigation of Mills Using ProFume – North America 2000.	Reg. Laboratories, Indianapolis, Dow AgroSciences, Indiana, USA	Y	N	N	Y (ii)	D	000329	February 2002
Barnekow, D.E., Byrne, S.L., Foster, D.R., Robb, C.K	Determination of Atmospheric Concentrations of Sulfuryl Fluoride Following Fumigation of Mills Using ProFume- North America 2001	Paragon Research Services, Fresno, CA, USA and MVTL Laboratories, New Ulm, Min, USA and Reg. Laboratories, Dow AgroSciences, Indianapolis, USA	Y	N	N	Y (ii)	D	010039	December 2001
Barnekow, D.W., Byrne, S.L., Foster, D.R.	Determination of Exposure Potential to Workers and Atmospheric Concentrations of Sulfuryl Fluoride During and Following Fumigation of Mills Using ProFume – North America 2002	Paragon Research Services, Fresno, CA, USA and MVTL Laboratories, New Ulm, MN, USA and Reg. Laboratories-Indianapolis Lab, Dow AgroSciences LLC, Indianapolis, IN, USA	Y	N	N	Y (ii)	D	020039	June2002
Blaschke, U.	Sulfuryl Fluoride, Determination of Atmospheric Concentrations of Sulfuryl Fluoride and Occupational Exposure of Fumigators during the structural Fumigation of a Mill using ProFume Germany 2002	Huntingdon Life Sciences, Ltd, Huntingdon, UK	Y	N	N	Y (ii)	D	DOS 299/023404	July 2002

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
Bradley, G. J Landry, T. D. Battjes, J. E. Quast, J. F.	Sulfuryl Fluoride: Four-Hour Dermal Vapor Exposure in Fischer 344 Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-036 K-16399-36 K-016399-036A K-0L6399-036B	November 1990
Breslin, W. J. Liberacki, A. B. Kirk, H. D. Bradley, G. J. Crissman, J. W.	Sulfuryl Fluoride: Two-Generation Inhalation Reproduction Study in Sprague-Dawley Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-042	January 1992
Burns,C.J., Maurissen,J.P., Eisenbrandt,D.L.	Review of Publication: Health Effects Associated With Sulfuryl Fluoride and Methyl Bromide Exposure Among Structural Fumigation Workers. Calvert,G.M., Mueller,C.A., Fajen,J.M., Chrislip,D.W., Russo,J., Briggle,T., Fleming,L.E., Suruda,A.J., Steenland,K. Amer J. Public Health **: 1774-1780, 1998	The Dow Chemical Company, Midland, Michigan, USA	N	N	N	N	D	P12	July 2002
Eisenbrandt, D. L. Williams, D. M. Albee, R. R. Streeter, C. M.	Sulfuryl Fluoride (Vikane* Gas Fumigant): An Ultrastructural Assessment of the Lungs of Rats Exposed to High Concentrations of Sulfuryl Fluoride	Dow Chemical Company, Midland	Y	N	Y	Y (ii)	D	HET K-016399-023	October 1987

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
Eisenbrandt, D.L., Nitschke, K.D., Streeter, C.M. & Wolfe, E.L.	Sulfuryl Fluoride (Vikane* Gas Fumigant): 2-Week Inhalation Toxicity Probe with Rats and Rabbits	Dow Chemical, Midland	Y	N	Y	Y (ii)	D	None	April 1985
Eisenbrandt,D.L., Burns, C., Hanley,T.R., Marable,B., Marty,S., Maurissen,J., Wright,J.	A Critical Review of Scientific Publications Related to Fluoride and a Response to Comments on Risk Assessment	Regulatory Laboratories, Dow AgroSciences, Indianapolis, Indiana, USA	N	N	N	N	D	GHC-5496	August 2002
Gollapudi, B. B. McClintock, M. L. Nitschke, K. D.,	Evaluation of Sulfuryl Fluoride in the Mouse Bone Marrow Micronucleus Test (in vivo)	Dow Chemical Company, Midland	Y	N	Y	Y (ii)	D	TXT: K-016399-033	February 1990
Gollapudi, B. B. McClintock, M. L. Zempel, J. A.	Evaluation of Sulfuryl Fluoride in the Rat Hepatocyte Unscheduled DNA Synthesis (UDS) Assay	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-043	October 1991
Gollapudi, B. B. Samson, Y. E. Zempel, J. A.	Evaluation of Sulfuryl Fluoride in the Ames Salmonella/Mammalian-Microsome Bacterial Mutagenicity Assay	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	TXT:K-016399-037	August 1990
Gollapudi, B.B., Linscombe, V.A., Jackson, K.M., DeLisle, T.H., Krieger, S.M., Rick, D.L.	Evaluation of Sulfuryl Fluoride in an In Vitro Chromosomal Aberration Assay Utilizing Rat Lymphocytes	Toxicology & Environmental Research and Consulting, Dow Chemical Company, Midland, USA	Y	N	N	Y (ii)	D	001133	May 2002

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
Gollapudi, B.B., Linscombe, V.A., Schisler, M.R., DeLisle, T.H., Krieger, S.M., Rick, D.L.	Evaluation of Sulfuryl Fluoride in the Mouse Lymphoma (L5178Y TK +/-) Forward Mutation Assay	Toxicology & Environmental Research and Consulting, Dow Chemical Company, Midland, USA	Y	N	N	Y (ii)	D	001144	May 2002
Gorzinski, S. J. Streeter, C. M.	Effect of Acute Vikane* Exposure on Selected Physiological Parameters in Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET K-016399-021	November 1985
Hanley, T. R., Calhoun, L. L. Kociba, R. J., Cobel-Geard, S.R., Hayes, W.C., Ouellette, J.H., Scherbarth, L.M., Sutter, B.N., John, J.A.	Vikane*: Inhalation Teratology Study in Rats and Rabbits	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET K-16399-(15)	October 1981
Hanley, T. R., Calhoun, L. L. Kociba, R. J., Cobel-Geard, S.R., Hayes, W.C., Ouellette, J.H., Scherbarth, L.M., Sutter, B.N., John, J.A.	Vikane*: Inhalation Teratology Study in Rats and Rabbits	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET K-16399-(15)	October 1981

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Hanley, T.R., Calhoun, L.L., Cobel-Geard, S.R., Hayes,W.C., Murray, J.S., Kociba,R.J., John,J.A.	Vikane: Probe Teratology Study in Fischer 344 Rats and New Zealand white Rabbits	The Dow Chemical Company	N	N	Y	Y (ii)	D	HET K-16399-(14)	November 1980
Jones, G.E., Perkins, J.M.	Determination of Atmospheric Concentration of Sulfuryl Fluoride Following Fumigation of a Mill using ProFume – UK 2002	Agrisearch Uk Ltd, Melbourne, UK and Minnesota Valley Testing Laboratories, New Ulm, MN, USA	Y	N	N	Y (ii)	D	AF/6268/DE	July 2002
Mattson, J. L. Albee, R. R. Eisenbrandt, D. L. Nitschke, K. D.	Neurological Examination of Fischer 344 Rats exposed to Sulfuryl Fluoride (Vikane* Gas Fumigant) for 13 weeks	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-026	November 1986
Mattsson, J. L. Albee, R. R. Eisenbrandt, D. L.	Subchronic Neurotoxicity in Rats of the Structural Fumigant, Sulfuryl Fluoride	Health and Environmental Sciences, Dow Chemical , Midland. University of Arkansas for Medical Sciences. Little Rock, Arkansas	Y	Y	Y	N	P	Neurotoxicity & Teratology Vol. 10, No. 2, 1988, pp 127-133	March 1987

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
Maurissen,J.P., Burns,C.J.	Review of Publication: Neurobehavioral Evaluation of Soil and Structural Fumigators Using Methyl Bromide and Sulfuryl Fluoride. Anger,w.K., Moody,L., Burg,F., Brightwell,W.S., Taylor,B.J., Russo,J.M., Dickerson,N., Setzer,J.V., Johnson,B.L and Hicks,K. NeuroToxicol. 7: 137-156, 1986	The Dow Chemical Company, Midland, Michigan, USA	N	N	N	N	D	P11	July 2002
Mecchi, M.S.	Escherichia coli/Mammalian-Microsome Reverse Mutation Assay with a Confirmatory Assay with Sulfuryl Fluoride (gas)	Convance Laboratories Inc., Vienna, VA 22182, USA	Y	N	N	Y (ii)	D	011207, 23357-0-409OECD	April 2002
Mendrala, A.L., Markham, D.A., Clark, A.J., Krieger, S.M., Houtman, C.E., Rick, D.L.	Sulfuryl Fluoride: Pharmacokinetics and Metabolism in Fischer 344 rats	Toxicology & Environmental Research and Consulting The Dow Chemical Company, Midland, USA	Y	N	Y	Y (ii)	D	DECO HET K-016399-059 / 001166	May 2002
Miller, R. R. Calhoun, L. L. Keyes, D. G.	Sulfuryl Fluoride (Vikane* Fumigant) An LC50 Determination	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-013	August 1980
Nitschke, K. D. Beekman, M. J. Quast, J. F.	Sulfuryl Fluoride: 13-week Inhalation Toxicity Study in Beagle Dogs	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-041 K-016399-041A	February 1992

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Nitschke, K. D. Dittenber, D. A. Eisenbrandt, D. L.	Sulfuryl Fluoride (Vikane* Gas Fumigant) 13-Week Inhalation Toxicity Study With Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-025R	November 1987
Nitschke, K. D. Gollapudi, B. B.	Response to U.S. EPA Comments on the Study entitled " Evaluation of Sulfuryl Fluoride in the Mouse Bone Marrow Micronucleus Test"	Dow Chemical Company, Midland	N	N	N	Y (ii)	D	TXT: K-016399-033	January 1991
Nitschke, K. D. Lomax, L. G.	Sulfuryl Fluoride: Acute LC50 Study with B6C3F1 Mice	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-028 K-016399-028A K-016399-028B	March 1989
Nitschke, K. D. Miller, R. R.	Sulfuryl Fluoride (Vikane* Gas Fumigant): Effects of Treatment With Calcium Gluconate or Anticonvulsants on Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET K-016399-024	April 1985
Nitschke, K. D. Quast, F. F.	Sulfuryl Fluoride: Two Week Inhalation toxicity Study in Beagle Dogs	Dow Chemical Company Midland	Y	N	Y	Y (ii)	D	K-016399-038	April 1991
Nitschke, K. D. Quast, J. F.	Sulfuryl Fluoride: Acute LC50 Study with CD-1 Mice	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-031; K-016399-031A; K-016399-031B	December 1990

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Nitschke, K. D. Quast, J. F.	Sulfuryl Fluoride: Thirteen Week Inhalation Toxicity Study in CD-1 Mice	Dow Chemical Company, Midland	Y	N	Y	Y (ii)	D	K-016399-032	December 1993
Nitschke, K. D. Zimmer, M. A. Eisenbrandt, D. L.	Sulfuryl Fluoride (Vikane* Gas Fumigant): 13-Week Inhalation Toxicity Study With Rabbits	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-025B	November 1987
Nitschke, K.D., Quast, J.J.	Sulfuryl Fluoride: Two-Week Inhalation Toxicity Study in CD-1 Mice	Toxicology & Environment Research And Consulting, The Dow Chemical Company, Midland, Michigan, USA.	Y	N	Y	Y (ii)	D	DECO HET K-016399-029	February 2002
Perkins, J.M.	Determination of Atmospheric Concentrations of Sulfuryl Fluoride Following Fumigation of a Mill using ProFume – UK 2000	Dow AgroSciences, Letcombe Laboratories, Wantage, UK and Minnesota Valley Testing Laboratories (MVTL) New Ulm, MN, USA	Y	N	N	Y (ii)	D	000377	July 2002
Perkins, J.M.	Determination of Atmospheric Concentrations of Sulfuryl Fluoride following Fumigation of a Mill using ProFume – Germany 2000	Dow AgroSciences, Letcombe Laboratory, Wantage, UK and Minnesota Valley Testing Laboratories, New Ulm, MN, USA	Y	N	N	Y (ii)	D	000303	July 2002
Perkins, J.M.	Determination of Atmospheric Concentrations of Sulfuryl Fluoride following Fumigation of a Mill using ProFume – Italy 2001	Dow AgroSciences, Letcombe Laboratory, Wantage, UK and Minnesota Valley Testing Laboratories (MVTL), New Ulm , MN, USA	Y	N	N	Y (ii)	D	010073	July 2002
Quast, J. F. Beekman, M. J. Nitschke, K. D.	Sulfuryl Fluoride: One Year Inhalation Toxicity Study In Beagle Dogs	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-044	October 1993

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
Quast, J. F. Bradley, G. J. Nitschke, K. D.	Sulfuryl Fluoride: 2-Year Inhalation Chronic Toxicity Oncogenicity Study in Fischer 344 Rats	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET-K-016399-040	August 1993
Quast, J.F. Bradley, G. J. Nitschke, K. D.	Sulfuryl Fluoride: 18 Month Inhalation Oncogenicity Study in CD-1 Mice	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	K-016399-039	August 1993
Spencer, P. J. Bradley, G. J. Quast, J. F.	Sulfuryl Fluoride: Chronic Neurotoxicity Study in Fischer 344 Rats – Final Report	Dow Chemical Company, Midland	Y	N	Y	Y (i)	D	HET K-016399-040B	March 1994
Vernot, E.H., MacEwen J.D., Haun, C.C.,, Kinkead, R.R.	Acute Toxicity and Skin Corrosion Data for Some Organic and Inorganic Compounds and Aqueous Solutions (University of California, Irvine, Toxic Hazards Research Unit, Overlook Branch, Dayton, Oh8io 45431)	Toxicology and Applied Pharmacology 42, 417-423 (1977)	N	Y	N	Y (ii)	D	None	January 1977

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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
Cady, G.H., Misra S.	Hydrolysis of Sulfuryl Fluoride	Department of Chemistry, University of Washington, Seattle	N	Y	N	N	P	Inorganic Chemistry, Vol. 13, No. 4, 1974	April 1974
Kirk, A.D, Yaroch, A.M., Rick, D.L., McClymont, E.L., Krieger, S.M.	Sulfuryl Fluoride: An Acute Toxicity Study with the Daphnid, Daphnia magna Straus	Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA	Y	N	N	Y (ii)	D	011146	January 2002
Kirk, H.D., McClymont, E.L., McFaden, L.G., Rick, D.L., Yaroch, A.M.	Sulfuryl Fluoride: An Acute Toxicity Study with the Zebra-Fish, Brachydanio rerio, Hamilton-Buchanan	Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA	Y	N	Y	Y (ii)	D	011147R	March 2002
Kirk, H.D., Rick, D.L., Krieger, S.M., McFadden, L.G.	Sulfuryl Fluoride: Growth Inhibition Test with the Freshwater Green Alga, Selenastrum capricornutum Printz.	Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA	Y	N	N	Y (ii)	D	011145	January 2002
Krieger, M.S.	Hydrolysis of Sulfuryl Fluoride (SO_2F_2)	Regulatory Laboratories, Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054	N	N	N	Y (ii)	D	GH-C 5346	November 2001
Krieger, M.S.	Atmospheric Fate and Global Warming Potential of Sulfuryl Fluoride (SO2F2)	Regulatory Laboratories, Dow AgroSciences, Indianapolis, Indiana, USA	N	N	N	Y (ii)	D	GH-C 5308	February 2002

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
Krieger, M.S.	Environmental Fugacity Modeling of Sulfuryl Fluoride (SO2F2)	Regulatory Laboratories, Dow AgroSciences, Indianapolis, Indiana, USA	n	n	n	Y (ii)	D	GH-C 5307	November 2001

Classification and Labelling

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
Anon	Package Material Specification, Valve – Vikane Cylinders	The Dow Chemical Company and Superior Valve Company	N	N	N	N	D	00014268	January 1995
Friese, D.D.	Corrosion Rates of Steel Cylinders in Vikane (Fumigant) Service	Dow Chemical, Pittsburg, Ca, USA	N	N	N	Y (ii)	D	DECO GB 3928 / CRI 2002000177	November 2001
Ryan, B.	Vikane Cylinder Hydrotester Operating Procedure	Dow AgroSciences, Pittsburgh, Ca, USA	N	N	N	N	D	None	