None of these methods were able to discriminate. Exposure to amorphous silica dust may induce a mild small airway disease, only in comparison to a control group. (Referenced and summarised in Document IIIA, Annex point IIA, VI, 6.5 – study summary 2 of 2).

Repeated dose, inhalation
Reuzel et al. exposed Wistar rats to up to 30 mg/m^3 amorphous silica by inhalation for 90 days. It was found that amorphous silicas did not induce persistent granulomas and the adverse affects in the respiratory tract partly or completely regressed. (Referenced and summarised in Document IIIA, Annex point IIA, VI, 6.4 – Study summary 1 of 2).

Johnston et al. exposed Fischer-344 rats to 50 mg/m^3 amorphous silica by inhalation for 90 days. It was found that amorphous silicon dioxide did not cause gene mutation, partly because of its low biopersistence and that the effects of exposure were reversible as demonstrated by the post-exposure results. (Referenced and summarised in Document IIIA, Annex point IIA, VI, 6.4 – Study summary 2 of 2).

Carcinogenicity
Takizawa et al. orally administered 0, 0.125, 2.5 and 5% amorphous silica to $B_6C_3F_1$ mice and Fisher rats 93 weeks and 103 weeks respectively and found that repeated oral administration produced no significant treatment-related effects. (Referenced and summarised in Document IIIA, Annex point IIA, 6.7 – Study summary 1 of 1).

Additionally, a review is available in the public domain of an unpublished study on the effects of amorphous silicon dioxide on multiple generations of rats. This study shows that there are no adverse effects to either generation when fed 100 mg/kg bw per day. Although this is an unpublished reference and therefore not useful for the risk assessment, it is considered suitable as supporting evidence for this data end point.

Conclusion
It has been demonstrated that the low level of exposure to silicon dioxide during its use as an insecticide (PT18) indicates that it is not scientifically necessary to conduct a multi-generations study on silicon dioxide as it will not add any useful information to the risk assessment. It has been shown in the human risk assessment that compared to exposures *via* the diet and the environment, exposure from silicon dioxide as an insecticide is insignificant. The risk assessment for human exposure to silicon dioxide, when applying the representative product RID Insect Powder shows that exposure to silicon dioxide does not exceed agreed, well established maximum exposure limits for safe working conditions with silicon dioxide and nuisance dust. The toxicological profile of silicon dioxide has been well established with a large body of data available in the public domain. The operator exposure limits that have been set for nuisance particles and dusts are also based on a large amount of available data. As shown above, data is available on the effects of exposure to amorphous silicon dioxide and this data shows that there are no lasting adverse effects. Although this data has its limitations and there are no studies available performed to specific guidelines which consider chronic toxicity or carcinogenicity, it is considered sufficient to address the toxicity of silicon dioxide particularly given the levels of exposure expected to silicon dioxide through other, non-biocidal uses of silicon dioxide including its use in food.

3.9 NEUROTOXICITY

Remark	Reference
It is not scientifically necessary to submit a neurotoxicity study for silicon dioxide, because the "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that this test is only required if there are any indications that the active substance may have neurotoxic properties. The safety profile of amorphous silicon dioxide is well established (see Document IIIA, Section 6.1.1 for further details) and there is a substantial volume of information available for silicon dioxide. The data available is in general agreement, all showing that amorphous silicon dioxide *per se* is intrinsically biologically inert. There is no data available which indicates that silicon dioxide may have neurotoxic properties. Generation of test data to determine neurotoxic effects of silicon dioxide is therefore not considered scientifically necessary.	Document IIIA, Section 6.9

3.10 HUMAN DATA

Effects of exposure to silicon dioxide in man are well reported in the product literature. This data has been summarised in Document IIIA, Sections 6.1.3, 6.4.3, 6.5 and 6.12. The key results for man include the following:

There is a substantial volume of data available on the toxicity of amorphous silicon dioxide, *via* both the oral and inhalation route. For man, acute oral LD_{50} has been estimated to be greater than 15000 mg/kg (see Document IIIA, Section 6.1.1. for further details).

As regards acute inhalation toxicity, even at the maximum attainable concentration in air (477 mgm^{-3}), no fatalities were caused amongst rats (see Document IIIA, Section 6.1.3 for further details).

There are no reported carcinogenic, species specific, reproduction, immunotoxic or hormone related effects for amorphous silicon dioxide. It is on this basis that it is not necessary to submit additional data regarding toxicity of amorphous silicon dioxide.

3.11 OTHER TOXICOLOGICAL EFFECTS

Remark	Reference
There are no reported toxicity effects of sufficient concern to justify further investigation by a mechanistic study. There are no reported carcinogenic, species specific, reproduction, immunotoxic or hormone related effects for amorphous silicon dioxide. It is on this basis that it is not necessary to submit additional data regarding any mechanism of silicon dioxide toxicity.	Document IIIA, Section 6.10
The major route of exposure to amorphous silicon dioxide from its use as an insecticide (PT18) is by inhalation. Therefore data on the parenteral administration of amorphous silicon dioxide has not been submitted.	Document IIIA, Section 6.11
It is not necessary to submit tests considering the toxicity of silicon dioxide in food and feeding stuffs because amorphous silicon dioxide as marketed by Rentokil Initial for use as an insecticide (PT18) is an approved food additive with Generally Regarded As Safe (GRAS) status. Therefore its exposure to food does not pose any risk.	Document IIIA, Section 6.14
Amorphous silicon dioxide is a stable compound (melting point >1500°C; solubility ≈100mg/L. Amorphous silicon dioxide has been shown not to produce any non mammalian-metabolite substances (see Document IIIA, Section A6.2 for further details). In addition, it has been shown that under test conditions, animals tested with amorphous silicon dioxide do not exhibit signs or symptoms suggesting interference with absorption of other dietary components as demonstrated by the lack of effect on food intake and weight gain (see Document IIIA, Section A6.1.1 and Section A6.5 for further details).	Document IIIA, Section 6.15
The main exposure to amorphous silicon dioxide is *via* the inhalation and the oral route. This will be equally true when amorphous silicon dioxide has been formulated for use as an insecticidal (PT18) powder. The main hazard will be from the inhalation of the dust from any such product. Effects of amorphous silicon dioxide dust inhalation have been widely reported along with the effects from exposure *via* the oral route. These have been examined fully in alternate sections of this dossier (Document IIIA, Section 6.1.3, Section 6.4.3, Section 6.1.1 etc.). Therefore it is not deemed necessary to perform any other tests related to the exposure of humans as this will not add anything useful to the risk assessment.	Document IIIA, Section 6.16 Document IIIA, Section 6.17
Therefore it is not deemed necessary to generate further data as it will not provide any useful information for the risk assessment.	
It is not necessary to provide data on the toxic effect of metabolites from treated plants because silicon dioxide is not intended for use directly on plants or plant products.	

Section 7.1.1.1.1 Annex Point/TNsG Annex IIA, VII.7.6.2.1	**Hydrolysis as a function of pH and identification of breakdown products** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Technically not feasible** [4] **Scientifically unjustified** [ ] **Limited exposure** [ ] **Other justification** [ ]		
Detailed justification:	OECD Method 111: Hydrolysis as a function of pH states that the method is applicable only to substances for which the analytical method has sufficient accuracy [to detect >10% hydrolysis]. For silicon dioxide to be analysed in this test, it would involve colorimetry and would require the use of pH buffered solutions. Immediately the colorimetric solutions are prepared, the pH is altered, all silicon species that are present will be changed back to silicon dioxide at that pH. Therefore, the analysis of any change in silicon dioxide content of the test solutions is impossible. Considering the above arguments, it is not deemed possible to perform this test.	
Undertaking of intended data submission [ ]	Not applicable	

Section 7.1.1.1.1 Annex Point/TNsG Annex IIA, VII.7.6.2.1	**Hydrolysis as a function of pH and identification of breakdown products** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FROM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.1.1.2 Phototransformation in water including identity of transformation products

Annex Point IIA7.6.2.2

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Rentokil Initial plc, Felcourt, East Grinstead, West Sussex United Kingdom RH19 2JY
1.2.2		
1.2.3	Criteria for data protection	Data submitted to MS after 13 May 2000 on existing active substance for the purpose of its entry into Annex I.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes. OECD Guidelines for the Testing of Chemicals. Proposal for a New Guideline, Phototransformation of Chemicals in Water – Direct and Indirect Photolysis. Draft document August 2000
2.2	**GLP**	Yes
2.3	**Deviations**	No.

3 MATERIALS AND METHODS

3.1	**Test material**	As given in section 2
3.1.1	Lot/Batch number	GA5007
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Radiolabelling	Not applicable.
3.1.5	UV/VIS absorption spectra and absorbance value	See Figures 1-2
3.1.6	Further relevant properties	Solubility of test substance: 112.739 g/L
3.2	**Reference substances**	Spectra of holmium oxide and potassium dichromate (0.06 g in 1 litre 0.005 M sulphuric acid) were obtained as evidence of wavelength and photometric accuracy. The results obtained indicated that the instrument was performing within the specified limits.
3.3	**Test solution**	See table A7_1_1_2-1
3.4	**Testing procedure**	*Non-entry field*
3.4.1	Test system	See Table A7_1_1_2-2
3.4.2	Properties of light source	Not applicable. Theoretical screen performed only.
3.4.3	Determination of	Not applicable. Theoretical screen performed only.

	irradiance	
3.4.4	Temperature	Not applicable. Theoretical screen performed only.
3.4.5	pH	Not applicable. Theoretical screen performed only.
3.4.6	Duration of the test	Not applicable. Theoretical screen performed only.
3.4.7	Number of replicates	2
3.4.8	Sampling	The sample was stored at ambient temperature in its original container.
3.4.9	Analytical methods	Not applicable.
3.5	**Transformation products**	No
3.5.1	Method of analysis for transformation products	Not applicable.

4 RESULTS

4.1	**Screening test**	Performed. See table A7_1_1_2-3 and Fig. 5.
4.2	**Actinometer data**	Not applicable. Theoretical screen performed only.
4.3	**Controls**	Not applicable.
4.4	**Photolysis data**	*Non-entry field*
4.4.1	Concentration values	Not applicable. Theoretical screen performed only.
4.4.2	Mass balance	Not applicable. Theoretical screen performed only.
4.4.3	k^e_p	Not applicable. Theoretical screen performed only.
4.4.4	Kinetic order	Not applicable. Theoretical screen performed only.
4.4.5	k^e_p / k^a_p	Not applicable. Theoretical screen performed only.
4.4.6	Reaction quantum yield (ϕ^e_E)	Not applicable. Theoretical screen performed only.
4.4.7	k_{pE}	Not applicable. Theoretical screen performed only.
4.4.8	Half-life ($t_{1/2E}$)	Not applicable. Theoretical screen performed only.
4.5	**Specification of the transformation products**	Not applicable. Theoretical screen performed only.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	This study was performed in accordance with OECD Guidelines for the Testing of Chemicals. Proposal for a New Guideline, Phototransformation of Chemicals in Water – Direct and Indirect Photolysis. Draft document August 2000

Preparation of test solution

Information provided by the Sponsor indicated a water solubility of 112 mg/L after 5 days at 30°C. In order to prepare a saturated stock solution, a nominal concentration of 500 mg/L was prepared by adding 0.5 g of the test substance to 1000 mL deionised water. This stock solution was

placed into a waterbath and stirred for a minimum of 5 days at 30°C.

After at least 5 days the test solution was allowed to settle and cool to room temperature. Using glassware and minimal silicon tubing the solution was passed through a 0.45 µm nylon filter using a Watson Marlow peristaltic pump.

Test method

The method utilised a UV/visible, single-beam spectrophotometer which recorded the absorption differences between a solution of test substance and the solution in which it was contained (blank). The spectrum recorded was thus due to test substance. The UV spectra was then used to calculate molar absorption coefficients of test substance at wavelengths between 290 and 800 nm. Assuming the test substance adsorbed above the cutoff of solar irradiation at the earth's surface the maximum possible rate constant was then estimated.

Scan conditions

The prepared saturated solution was scanned using a 1 cm path length quartz cell. All spectra included in this report were obtained from a Perkin Elmer Lambda 11 UV/visible spectrophotometer. Scans were performed in the region 290 - 900 nm. Full details of instrument conditions are given in the Appendix.

An autozero of the blank was carried out before each blank scan. The sample scans were then run and compared with the blank scan.

Instrument check

Spectra of holmium oxide and potassium dichromate (0.06 g in 1 litre 0.005 M sulphuric acid) were obtained as evidence of wavelength and photometric accuracy. The results obtained indicated that the instrument was performing within the specified limits.

Theoretical screen (tier 1)

A preliminary scan demonstrated that a measurable absorbance was obtained from the saturated solution. The test solution was then scanned in duplicate as follows:

A full scan over the range 200-900 nm at 1 nm intervals

A scan from 290-325 nm at 0.1 nm intervals

A scan from 325 to 800 nm at 1 nm intervals.

The scans were obtained on 6 and 10 February 2006 (replicates 1 and 2).

Using absorbance values from the individual scans over the 290 to 800 nm range the maximum rate constant, minimum half-life and % loss over 30 days of test substance are estimated using the following equations:

$$\varepsilon_\lambda = \frac{A}{C \cdot l} \quad (1)$$

where,

ε_λ = the molar absorption coefficient (M^{-1} cm^{-1}) at wavelength λ

A = the measured absorbance by UV/visible spectrophotometry

C = the concentration of test substance (M)

l = the path length (cm)

Molar absorptivities are calculated for the appropriate wavelength intervals and wavelength centres, where the test substance absorbs light. The wavelength centre is defined as the midpoint of the interval range.

$k_{d(max)}$ (day^{-1}) = $\sum \varepsilon_\lambda L_\lambda$ (2)

$t_{1/2(min)}$ (day) = $0.693/k_{d(max)}$ (3)

where,

$k_{d(max)}$ = the maximum direct photolysis rate constant (day^{-1})

L_λ = the midseason solar irradiance (mmol photons cm^{-2} day^{-1}). It is related to the sunlight intensity in water and is proportional to the average light flux that is available to cause photoreaction in a wavelength interval centred at λ over a 24 hour day at specific latitude and season date.$t_{1/2(min)}$ = the minimum half-life

% loss over 30 days / nights solar = $100\{1-\exp[-k_{(solar)}(t=30d)]\}$

where,

$k_{(solar)}$ = pseudo first-order direct photolysis rate constant for test substance exposed to solar irradiation (day^{-1})

5.2 Results and discussion

The test substance gave an absorbance of approximately [redacted] at 295 nm. This gives a molar adsorption, ε [redacted] M^{-1} cm^{-1} (equation 1), therefore the maximum possible rate constant was estimated. In the absence of a measured concentration for the saturated solution, the concentration is assumed to be 112 mg/L, 1.87×10^{-3} M (given the molecular weight of SiO_2 of 60).

Calculations of the rate constants for each wavelength centre are given in Tables A7_1_1_1_2-4 to A7_1_1_1_2-7, the molar extinction coefficients as a function of wavelength are given in Figure 1 and scans are presented in Figures 2-5. L_λ values for summer and winter at 50°N were selected to be representative of seasonal extremes for mid European solar irradiance.

On calculation of the individual rate constants it was noted that the absorbance values recorded at the higher end of the spectrum were very close to those of the blank scans. The signal to noise ratio was therefore determined from a representative area for each of the blank scans and multiplied by 3 to give a minimum detectable absorbance for the instrument. These were determined to be 0.0135 and 0.015 for replicates 1 and 2 respectively. Any values below these limits were then discounted from the calculation of the maximum rate constant (sum of the rate constants for each wavelength centre). In both cases all values above 390 nm were not included in the calculation.

The average maximum rate constants for the two replicates were 16 and 3 day^{-1} for summer and winter conditions at 50°N respectively. According to equation 3 this equates to a minimum half-life of 0.043 and 0.23 days, or 62 and 331 minutes for summer and winter respectively.

By substituting $k_{d(max)}$ for $k_{(solar)}$ in equation 4 it was determined that the

Section A7.1.1.1.2 **Phototransformation in water including identity of transformation products**

Annex Point IIA7.6.2.2

		maximum possible direct photolysis rate constant for the test substance in the near surface of a clear natural water exposed to an average daily solar photon flux would result in estimated direct photolysis losses greater than 50% of an initial concentration over 30 days/nights of sunlight exposure.
5.2.1	k^e_p	Not applicable.
5.2.2	K_{pE}	Not applicable.
5.2.3	ϕ^e_E	Not applicable.
5.2.4	$t_{1/2E}$	$t_{1/2(min)}$ = 0.043 day
5.3	**Conclusion**	The first tier test performed in this study is considered to have met all validity criteria. Given the estimated half-lives given above, calculations suggest that the test substance photolyses rapidly in both summer and winter conditions at 50°N. According to the OECD guideline this substance would be expected to proceed to further testing. However, it is felt that the calculations do not give a realistic estimate of photolysis for this substance. Firstly the absorbance and molar extinction coefficients above 295 nm are very low, such that the test substance would not be expected to photolyse. Secondly the calculations assume that the test substance absorbs every photon of light, ie the quantum yield is equal to 1. In reality the quantum yield is generally much less than 1 (usually <0.1 and sometimes <0.01). The maximum rate constant, as determined by further testing would therefore be considered to be slower. A further consideration is that in order to perform the full study the concentration of the test substance must be measured. In the absence of a method able determine silicon dioxide (to determine measured concentrations in other studies on this substance silicon levels were measured), it would be impossible to determine losses of the parent. It was therefore considered inappropriate to perform further testing as the study is technically not possible to perform under guidance from the Biocidal Products Directive.
5.3.1	Reliability	1
5.3.2	Deficiencies	Yes. Higher tier testing was not performed for the reasons given in "5.3 Conclusion" above.

Section A7.1.1.1.2 Phototransformation in water including identity of transformation products

Annex Point IIA7.6.2.2

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and Methods	*State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_1_1_2-1: Description of test solution and controls

Criteria	Details
Purity of water	Deionised water.
Preparation of test chemical solution	Information provided by the Sponsor indicated a water solubility of 112 mg/L after 5 days at 30°C. In order to prepare a saturated stock solution, a nominal concentration of 500 mg/L was prepared by adding 0.5 g of test substance to 1000 ml deionised water. This stock solution was placed into a waterbath and stirred for a minimum of 5 days at 30°C. After at least 5 days the test solution was allowed to settle and cool to room temperature. Using glassware and minimal silicon tubing the solution was passed through a 0.45 µm nylon filter using a Watson Marlow peristaltic pump.
Test concentrations (mg a.s./L)	500 mg/L (nominal value).
Temperature (°C)	Not reported.
Preparation of a.s. solution	Not applicable.
Controls	Standard solution blanks.
Identity and concentration of co-solvent	Not applicable.

Table A7_1_1_2-2: Description of test system

Criteria	Details
Laboratory equipment	The prepared saturated solution was scanned using a 1 cm path length quartz cell. All spectra included in this report were obtained from a Perkin Elmer Lambda 11 UV/visible spectrophotometer. Scans were performed in the region 290 - 900 nm. Full details of instrument conditions are given in the Appendix. An autozero of the blank was carried out before each blank scan. The sample scans were then run and compared with the blank scan.
Test apparatus	Spectra were measured using an ultra-violet spectrophotometer. This was done using the instrument conditions shown below. Instrument: Perkin Elmer Lambda 11 UV/visible spectrophotometer Mode: Abs X axis min-max (nm): 200-900 Y axis min-max (abs): 0-2.5 Sampling interval: 0.1 or 1 nm Scan speed: 30 nm min^{-1} Number of cycles: 2 Path length: 1 cm H Lamp: on *D_2 lamp*: on
Properties of artificial light source:	Not applicable.
Nature of light source	Not applicable.
Emission wavelenght spectrum	Not applicable.
Light intensity	Not applicable.
Filters	Not applicable.
Properties of natural sunlight:	Not applicable.
Latitude	Not applicable.
Hours of daylight	Not applicable.
Time of year	Not applicable.
Light intensity	Not applicable.
Solar irradiance (L_λ)	Not applicable.

Table A7_1_1_2-3: Screening test results

Absorption curve	See Figures 1-4
A_λ	See Tables A7_1_1_1_2-4 to A7_1_1_1_2-7
$\varepsilon_\lambda{}^c$	See Tables A7_1_1_1_2-4 to A7_1_1_1_2-7
k_{pEmax}	$k_{d\ (max)}$: See Tables A7_1_1_1_2-4 to A7_1_1_1_2-7
$t_{1/2Emin}$	Summer minimum half lfe = 0.043 days Winter minimum half life = 0.23 days
L_λ	See Tables A7_1_1_1_2-4 to A7_1_1_1_2-7

Table A7_1_1_2-4: Absorbance, and Theoretical Maximum Rate Constant for Summer at 50°N Replicate 1

Wavelength	Absorbance	ε_λ	L_λ	εL_λ
297.5	0.0867	46	2.86E-05	0.00
300	0.0811	43	1.50E-04	0.01
302.5	0.0762	41	5.33E-04	0.02
305	0.0713	38	1.39E-03	0.05
307.5	0.0663	35	2.89E-03	0.10
310	0.0617	33	5.05E-03	0.17
312.5	0.0570	30	7.75E-03	0.23
315	0.0527	28	1.08E-02	0.30
317.5	0.0490	26	1.40E-02	0.36
320	0.0455	24	1.71E-02	0.41
323.1	0.0418	22	3.12E-02	0.69
330	0.0339	18	1.10E-01	1.98
340	0.0268	14	1.40E-01	1.96
350	0.0212	11	1.57E-01	1.73
360	0.0177	9	1.74E-01	1.57
370	0.0148	8	1.86E-01	1.49
380	0.0138	7	1.99E-01	1.39
390	0.0148	8	1.87E-01	1.50
400[a]	0.0133	7	2.69E-01	1.88
410[a]	0.0120	6	3.55E-01	2.13
420[a]	0.0109	6	3.65E-01	2.19
430[a]	0.0092	5	3.52E-01	1.76
440[a]	0.0082	4	4.17E-01	1.67
450[a]	0.0078	4	4.69E-01	1.88
460[a]	0.0073	4	4.75E-01	1.90
470[a]	0.0068	4	4.91E-01	1.96
480[a]	0.0067	4	5.03E-01	2.01
490[a]	0.0059	3	4.76E-01	1.43
500[a]	0.0058	3	4.85E-01	1.46
525[a]	0.0051	3	1.28	3.84
550[a]	0.0044	2	1.33	2.66
575[a]	0.0042	2	1.34	2.68
600[a]	0.0037	2	1.35	2.70
625[a]	0.0037	2	1.37	2.74
650[a]	0.0030	2	1.38	2.76
675[a]	0.0030	2	1.39	2.78
700[a]	0.0027	1	1.38	1.38
750[a]	0.0026	1	2.66	2.66
800[a]	0.0016	1	2.57	2.57
			$K_{d(max)}$	14 $days^{-1}$

a Values not used to calculate the maximum rate constant

Table A7_1_1_2-5: Absorbance, and Theoretical Maximum Rate Constant for Summer at 50°N Replicate 2

Wavelength	Absorbance	ε_λ	L_λ	εL_λ
297.5	0.0853	46	2.86E-05	0.00
300	0.0800	43	1.50E-04	0.01
302.5	0.0749	40	5.33E-04	0.02
305	0.0699	37	1.39E-03	0.05
307.5	0.0652	35	2.89E-03	0.10
310	0.0603	32	5.05E-03	0.16
312.5	0.0558	30	7.75E-03	0.23
315	0.0518	28	1.08E-02	0.30
317.5	0.0481	26	1.40E-02	0.36
320	0.0445	24	1.71E-02	0.41
323.1	0.0409	22	3.12E-02	0.69
330	0.0399	21	1.10E-01	2.31
340	0.0333	18	1.40E-01	2.52
350	0.0294	16	1.57E-01	2.51
360	0.0258	14	1.74E-01	2.44
370	0.0237	13	1.86E-01	2.42
380	0.0206	11	1.99E-01	2.19
390	0.0159	9	1.87E-01	1.68
400[a]	0.0145	8	2.69E-01	2.15
410[a]	0.0134	7	3.55E-01	2.49
420[a]	0.0124	7	3.65E-01	2.56
430[a]	0.0128	7	3.52E-01	2.46
440[a]	0.0123	7	4.17E-01	2.92
450[a]	0.0118	6	4.69E-01	2.81
460[a]	0.0112	6	4.75E-01	2.85
470[a]	0.0106	6	4.91E-01	2.95
480[a]	0.0105	6	5.03E-01	3.02
490[a]	0.0102	5	4.76E-01	2.38
500[a]	0.0098	5	4.85E-01	2.43
525[a]	0.0087	5	1.28	6.40
550[a]	0.0075	4	1.33	5.32
575[a]	0.0070	4	1.34	5.36
600[a]	0.0069	4	1.35	5.40
625[a]	0.0066	4	1.37	5.48
650[a]	0.0059	3	1.38	4.14
675[a]	0.0058	3	1.39	4.17
700[a]	0.0043	2	1.38	2.76
750[a]	0.0036	2	2.66	5.32
800[a]	0.0028	1	2.57	2.57
			$k_{d(max)}$	18 $days^{-1}$

a Values not used to calculate the maximum rate constant

Table A7_1_1_2-6: Absorbance, and Theoretical Maximum Rate Constant for Winter at 50°N Replicate 1

Wavelength	Absorbance	ε_λ	L_λ	εL_λ
297.5	0.0867	46	5.47E-08	2.52E-06
300	0.0811	43	4.17E-07	1.79E-05
302.5	0.0762	41	2.62E-06	1.07E-04
305	0.0713	38	1.34E-05	5.09E-04
307.5	0.0663	35	5.14E-05	1.80E-03
310	0.0617	33	1.49E-04	0.00
312.5	0.0570	30	3.43E-04	0.01
315	0.0527	28	6.52E-04	0.02
317.5	0.0490	26	1.07E-03	0.03
320	0.0455	24	1.57E-03	0.04
323.1	0.0418	22	3.39E-03	0.07
330	0.0339	18	1.45E-02	0.26
340	0.0268	14	2.12E-02	0.30
350	0.0212	11	2.53E-02	0.28
360	0.0177	9	2.96E-02	0.27
370	0.0148	8	3.30E-02	0.26
380	0.0138	7	3.65E-02	0.26
390	0.0148	8	3.49E-02	0.28
400[a]	0.0133	7	4.98E-02	0.35
410[a]	0.0120	6	6.54E-02	0.39
420[a]	0.0109	6	6.71E-02	0.40
430[a]	0.0092	5	6.47E-02	0.32
440[a]	0.0082	4	7.66E-02	0.31
450[a]	0.0078	4	8.62E-02	0.34
460[a]	0.0073	4	8.74E-02	0.35
470[a]	0.0068	4	8.95E-02	0.36
480[a]	0.0067	4	9.15E-02	0.37
490[a]	0.0059	3	8.62E-02	0.26
500[a]	0.0058	3	8.77E-02	0.26
525[a]	0.0051	3	2.28E-01	0.68
550[a]	0.0044	2	2.32E-01	0.46
575[a]	0.0042	2	2.28E-01	0.46
600[a]	0.0037	2	2.32E-01	0.46
625[a]	0.0037	2	2.42E-01	0.48
650[a]	0.0030	2	2.53E-01	0.51
675[a]	0.0030	2	2.61E-01	0.52
700[a]	0.0027	1	2.66E-01	0.27
750[a]	0.0026	1	5.22E-01	0.52
800[a]	0.0016	1	5.11E-01	0.51
			$k_{d(max)}$	2 $days^{-1}$

a Values not used to calculate the maximum rate constant

Table A7_1_1_2-7: Absorbance, and Theoretical Maximum Rate Constant for Winter at 50°N Replicate 2

Wavelength	Absorbance	ε_λ	L_λ	εL_λ
297.5	0.0853	46	5.47E-08	2.52E-06
300	0.0800	43	4.17E-07	1.79E-05
302.5	0.0749	40	2.62E-06	1.05E-04
305	0.0699	37	1.34E-05	4.96E-04
307.5	0.0652	35	5.14E-05	1.80E-03
310	0.0603	32	1.49E-04	0.00
312.5	0.0558	30	3.43E-04	0.01
315	0.0518	28	6.52E-04	0.02
317.5	0.0481	26	1.07E-03	0.03
320	0.0445	24	1.57E-03	0.04
323.1	0.0409	22	3.39E-03	0.07
330	0.0399	21	1.45E-02	0.30
340	0.0333	18	2.12E-02	0.38
350	0.0294	16	2.53E-02	0.40
360	0.0258	14	2.96E-02	0.41
370	0.0237	13	3.30E-02	0.43
380	0.0206	11	3.65E-02	0.40
390	0.0159	9	3.49E-02	0.31
400[a]	0.0145	8	4.98E-02	0.40
410[a]	0.0134	7	6.54E-02	0.46
420[a]	0.0124	7	6.71E-02	0.47
430[a]	0.0128	7	6.47E-02	0.45
440[a]	0.0123	7	7.66E-02	0.54
450[a]	0.0118	6	8.62E-02	0.52
460[a]	0.0112	6	8.74E-02	0.52
470[a]	0.0106	6	8.95E-02	0.54
480[a]	0.0105	6	9.15E-02	0.55
490[a]	0.0102	5	8.62E-02	0.43
500[a]	0.0098	5	8.77E-02	0.44
525[a]	0.0087	5	2.28E-01	1.14
550[a]	0.0075	4	2.32E-01	0.93
575[a]	0.0070	4	2.28E-01	0.91
600[a]	0.0069	4	2.32E-01	0.93
625[a]	0.0066	4	2.42E-01	0.97
650[a]	0.0059	3	2.53E-01	0.76
675[a]	0.0058	3	2.61E-01	0.78
700[a]	0.0043	2	2.66E-01	0.53
750[a]	0.0036	2	5.22E-01	1.04
800[a]	0.0028	1	5.11E-01	0.51
			$k_{d(max)}$	3 $days^{-1}$

a Values not used to calculate the maximum rate constant

Fig. 1 Test substance scan, Replicate 1

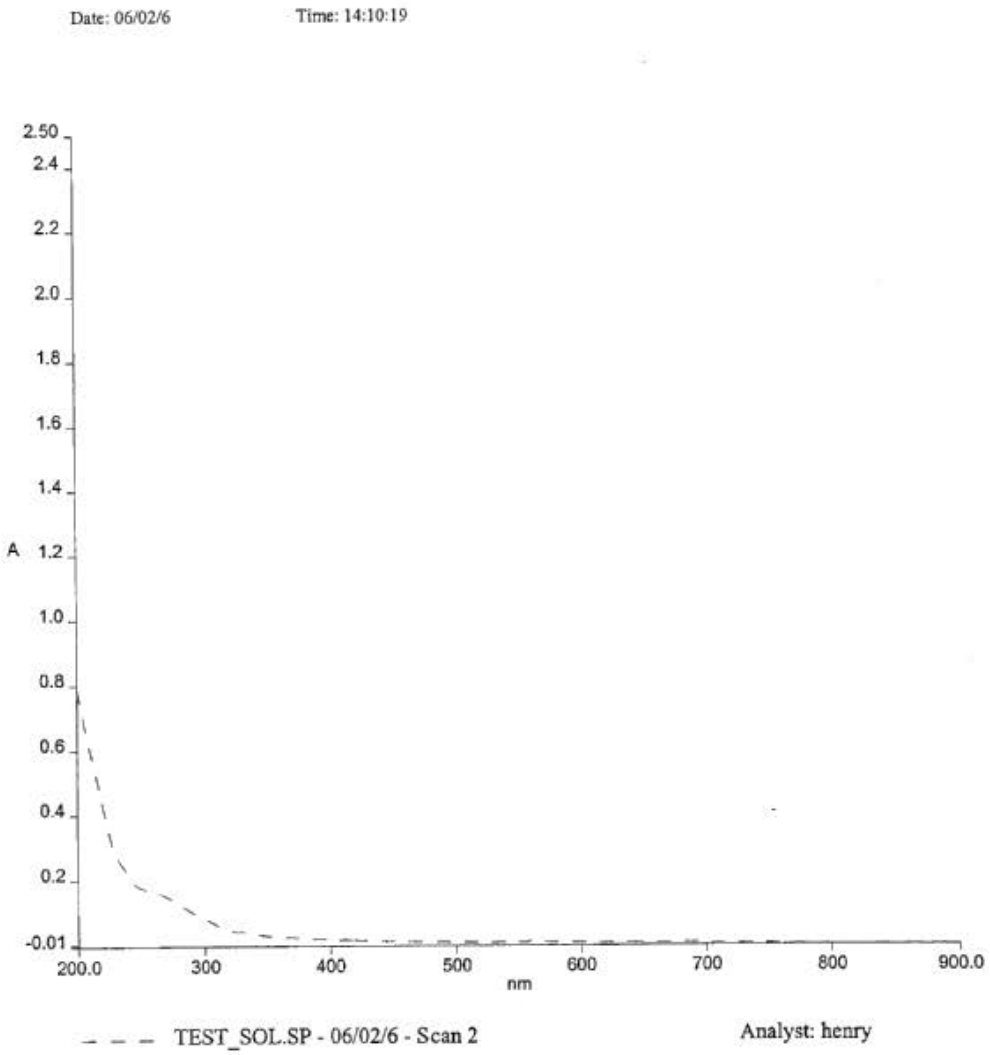


Fig. 2 Test substance scan, Replicate 2

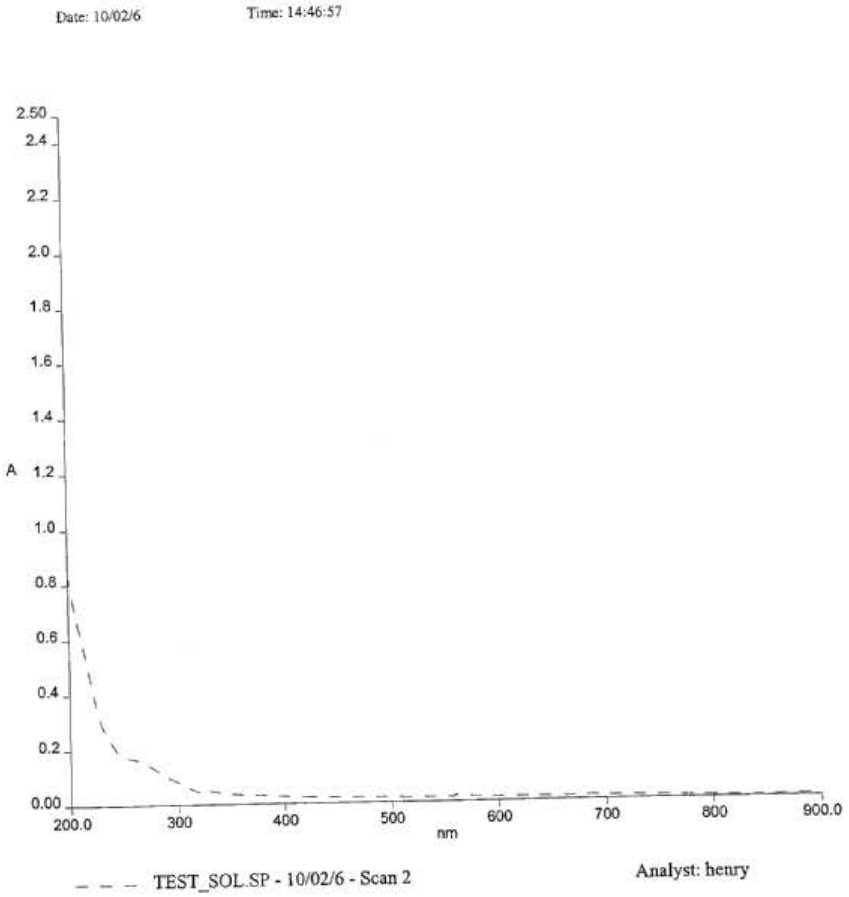


Fig. 3 Blank scan, Replicate 1

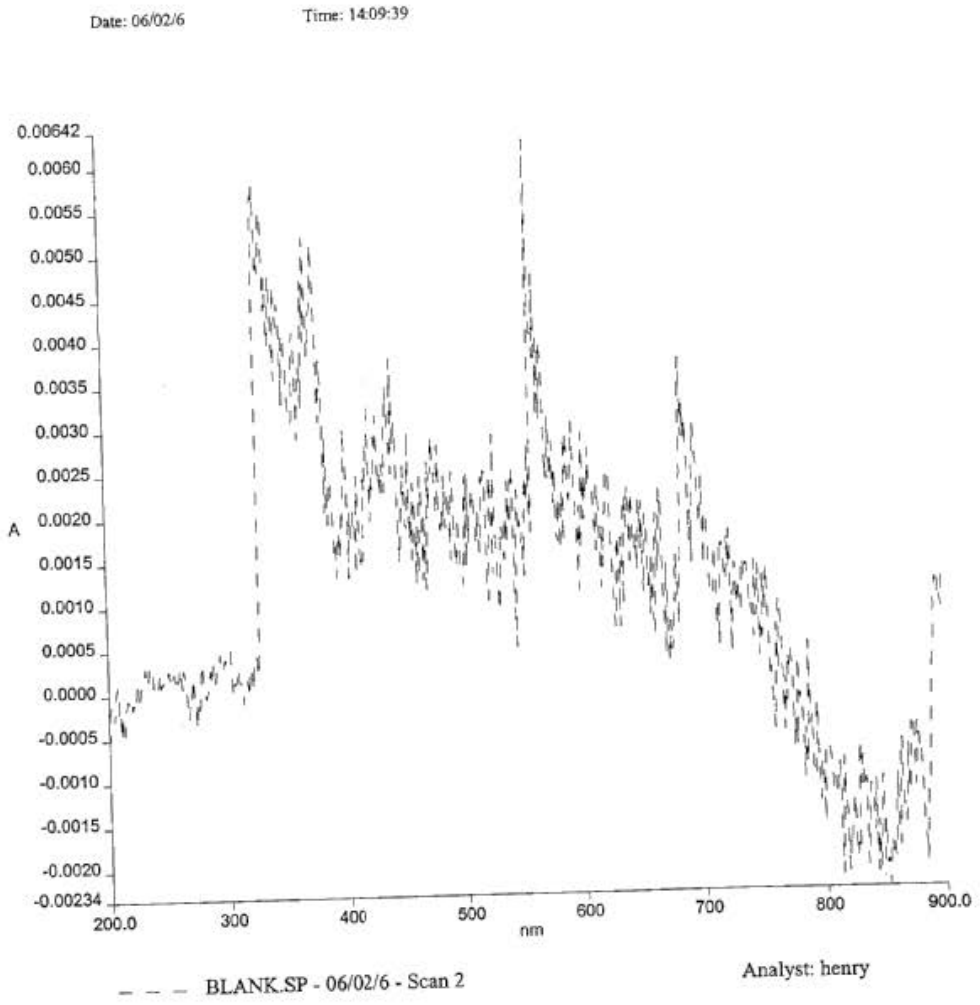


Fig. 4 Blank scan, Replicate 2

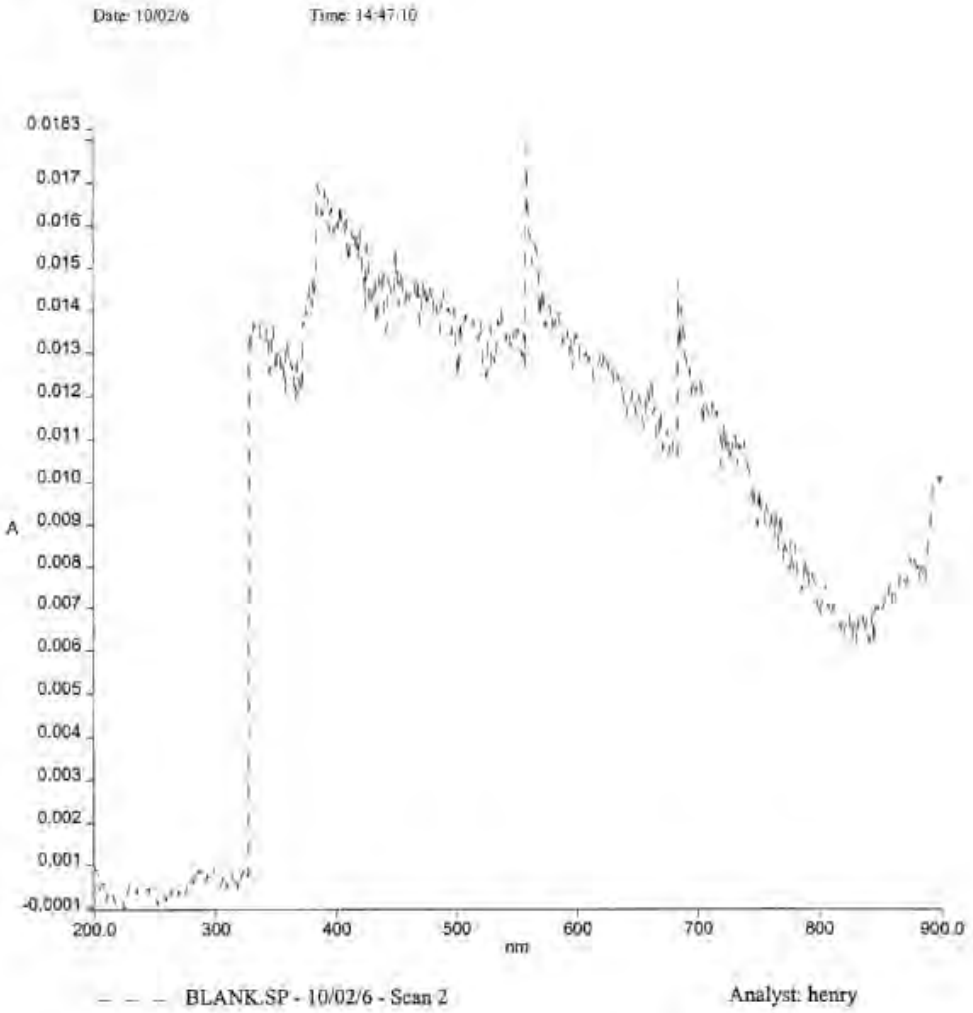
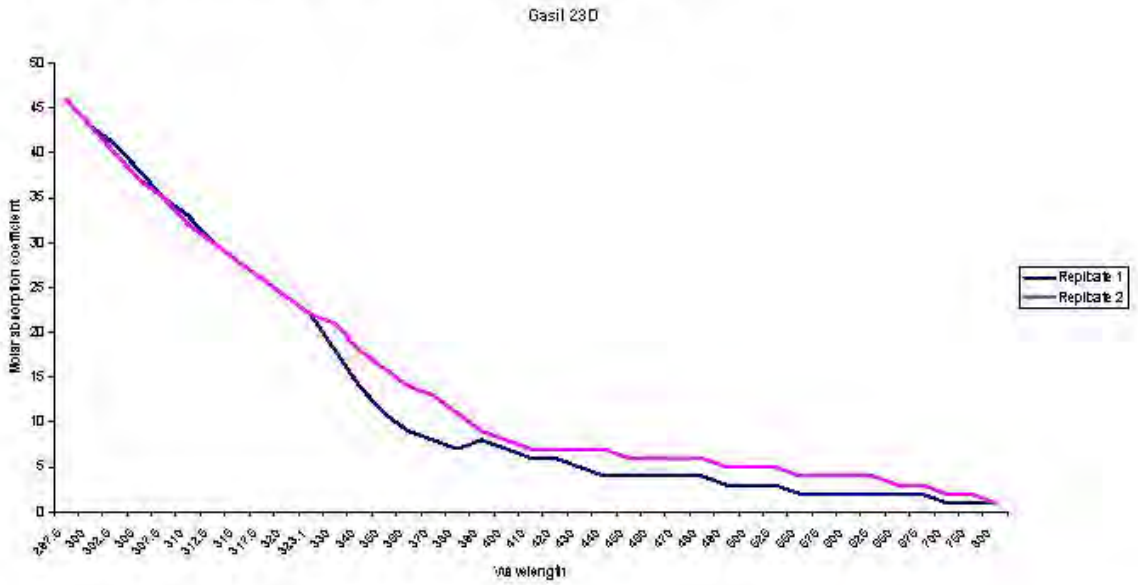


Fig. 5 Molar extinction coefficients as a function of wavelength



Section 7.1.1.2.1 Annex Point/TNsG Annex IIA, VII.7.6.1.1	**Ready biodegradability** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [4]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the approved EC method C4 (a –f) applies only to organic compounds. In addition, the "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that the ready biodegradation test is required of organic compounds. It is for the reasons given above that a ready biodegradation test for silicon dioxide has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FROM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.1.2.2 Annex Point/TNsG Annex IIA, VII.7.6.1.2	**Inherent biodegradability** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [4] **Scientifically unjustified** [4]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	It is not scientifically necessary to determine the inherent biodegradability of silicon dioxide for the following reasons: Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the inherent biodegradability of inorganic chemicals, because the approved EC method C9 and C12 applies only to water-soluble, non-volatile organic substances. While silicon dioxide is slightly soluble and non-volatile, it is an inorganic compound. It is for the reasons given above that an inherent biodegradation test for silicon dioxide has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FROM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.1.2.3 Annex Point/TNsG Annex IIIA, XII.2.1	**Biodegradation in seawater** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [✓]	**Technically not feasible** [✓] **Scientifically unjustified** [✓] **Other justification** [ ]	
Detailed justification:	It is not scientifically necessary to determine the biodegradability of silicon dioxide for the following two reasons: 1. Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the process applies only to organic compounds. 2. Biodegradation in seawater is not required as silicon dioxide is not intended to be either used or released into marine environments. For these purposes, it is intended that silicon dioxide be used as a biocide in a closed system. It is for the reasons given above that a biodegradation test for silicon dioxide in seawater has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.2 Annex Point/TNsG Annex IIIA, XII.2.1	**Rate and route of degradation in aquatic systems including identification of metabolites** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	Additional testing of the degradation of silicon dioxide in aquatic systems is scientifically unjustified on the following basis: 1. Testing for the ready biodegradability (A7.1.1.2.1) of silicon dioxide is scientifically unjustified. Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the approved EC method for ready biodegradability (EC method C4 a-f) applies only to organic compounds. In addition, the "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that the ready biodegradation test is required of organic compounds. 2. Inherent biodegradability (A7.1.1.2.2) is technically not feasible to perform on silicon dioxide as the approved EC test methods C9 and C12 are designed to work with water-soluble, non-volatile organic substances. While silicon dioxide is slightly soluble and non-volatile, it is an inorganic compound. Notwithstanding the above, the preliminary risk assessment for exposure to water does not indicate the need to conduct additional studies on the fate and behaviour of silicon dioxide in the aquatic compartment. It is for the reasons given above that additional test data about the degradation of silicon dioxide in aquatic systems has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.1.2 Annex Point/TNsG Annex IIIA, XII.2.1	**Rate and route of degradation in aquatic systems including identification of metabolites** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.2.1.1 Annex Point/TNsG Annex IIIA, XI.-2.1	**Biological sewage treatment – aerobic biodegradation** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [✓]	**Other justification** [ ]	
Detailed justification:	It is not scientifically necessary to determine the aerobic biodegradation of silicon dioxide in sewage for the following reason: Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the process applies only to organic compounds. It is for this reason that a test to determine the aerobic biodegradation of silicon dioxide in sewage has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Section A7.1.2.1.1 Annex Point/TNsG Annex IIIA, XI.-2.1	**Biological sewage treatment – aerobic biodegradation** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.2.1.2 Annex Point/TNsG Annex IIIA, XII.2.1	**Biological sewage treatment - anaerobic biodegradation** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✔]	
Limited exposure [✔]	**Other justification** [ ]	
Detailed justification:	It is not scientifically necessary to determine the anaerobic biodegradation of the silicon dioxide in sewage for the following two reasons: 1. Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the process applies only to organic compounds. 2. Anaerobic biodegradation in biological sewage treatment is not applicable here, as silicon dioxide is not intended to be exposed to anaerobic conditions, such as manure storage facilities in animal housing. For these purposes, it is intended that silicon dioxide be used as a biocide in a closed system. It is for these reasons that a test to determine the anaerobic biodegradation of silicon dioxide in sewage has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Section A7.1.2.1.2 Annex Point/TNsG Annex IIIA, XII.2.1	**Biological sewage treatment - anaerobic biodegradation** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.2.2.1 Annex Point/TNsG Annex IIIA, XII.2.1	**Biodegradation in freshwater – Aerobic aquatic degradation study** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The testing of biodegradation of silicon dioxide in aquatic systems is scientifically unjustified on the following basis: 1. Testing for the ready biodegradability (A7.1.1.2.1) of silicon dioxide is scientifically unjustified. Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the approved EC method for ready biodegradability (EC method C4 a-f) applies only to organic compounds. In addition, the "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that the ready biodegradation test is required of organic compounds. 2. Inherent biodegradability (A7.1.1.2.2) is technically not feasible to perform on silicon dioxide as the approved EC test methods C9 and C12 are designed to work with water-soluble, non-volatile organic substances. While silicon dioxide is slightly soluble and non-volatile, it is an inorganic compound. It is for these reasons that an aerobic aquatic biodegradation study for silicon dioxide has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.1.2.2.1 Annex Point/TNsG Annex IIIA, XII.2.1	**Biodegradation in freshwater – Aerobic aquatic degradation study** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.2.2.2 Annex Point/TNsG Annex IIIA, XII.2.1	**Biodegradation in freshwater – water/sediment degradation study** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [✓]	**Other justification** [ ]	
Detailed justification:	The testing of the biodegradation of silicon dioxide in freshwater/sediment is scientifically unjustified because silicon dioxide, under normal conditions of use in Rentokil Initial's insecticide (PT18) products will not be applied directly or indirectly to the sediment in aquatic systems. In addition: 1. Testing for the ready biodegradability (A7.1.1.2.1) of silicon dioxide is scientifically unjustified. Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the approved EC method for ready biodegradability (EC method C4 a-f) applies only to organic compounds. In addition, the "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that the ready biodegradation test is required of organic compounds. 2. Inherent biodegradability (A7.1.1.2.2) is technically not feasible to perform on silicon dioxide as the approved EC test methods C9 and C12 are designed to work with water-soluble, non-volatile organic substances. While silicon dioxide is slightly soluble and non-volatile, it is an inorganic compound. It is for these reasons that a study to determine the biodegradation of silicon dioxide in freshwater/sediment has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.1.2.2.2 Annex Point/TNsG Annex IIIA, XII.2.1	**Biodegradation in freshwater – water/sediment degradation study** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.3 Annex Point Annex IIIA, XII, 2.2	**Adsorption/desorption screening test** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [4]	**Technically not feasible** [ ] **Scientifically unjustified** [4]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	Amorphous silicon dioxide is not expected to reach the soil compartment (see Document IIIA, Section 2.10 for exposure assessment) and there are no indications that it will bioaccumulate (see Document IIIA, Section 7.4.2 and Section 2.10 for further details). Also a value for log K_{oc} can be calculated. In the *Technical Guidance Document on Risk Assessment in support of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market*, (TGD) Chapter 3, it states that K_{oc} can be estimated using K_{ow} for non-ionic substances using QSARS. Log K_{ow} has been calculated for silicon dioxide to be 0.53 (see Document IIIA, Section 3.9 for calculation). Using LOGKOW as the most appropriate QSAR from Table 4, Page 26, Chapter 4 of the TGD gives the equation for the estimation of log K_{oc} for a non-hydrophobic substance as: $\log K_{oc} = 0.52 \log K_{ow} + 1.02$ Therefore for silicon dioxide: $\log K_{oc} = (0.52 \times 0.53) + 1.02 = 1.30$ and a standard error of 0.56 giving: $\log K_{oc} = 1.30 \pm 0.56$ As this calculation is expected to reflect a result determined by experimentation, it is not deemed scientifically necessary to perform any further studies.	
Undertaking of intended data submission [ ]	Not applicable	

Section 7.1.3 Annex Point Annex IIIA, XII, 2.2	**Adsorption/desorption screening test** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FROM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.4 Annex Point/TNsG Annex IIIA, XII 2.2	**Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary.** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [✓]	**Other justification** [ ]	
Detailed justification:	It is not scientifically necessary to conduct further studies on the adsorption and desorption of amorphous silicon dioxide in water sediment systems because the preliminary risk assessment indicates it is scientifically unjustified, and not necessary due to prerequisites fulfilled on limited exposure and toxicity profile. 1. Amorphous silicon dioxide does not biodegrade (refer to data end points Document IIIA Section 7.1.1.2.1 and Document IIIA Section 7.1.1.2.2) making it scientifically unnecessary to determine the aerobic biodegradation of amorphous silicon dioxide in soil because of its inherent characteristics. 2. Notwithstanding the above, it is not scientifically necessary to determine the aerobic biodegradation of amorphous silicon dioxide in soil due to prerequisites fulfilled on limited exposure and toxicity profile. This is because: a. Amorphous silicon dioxide as used as an insecticide (PT18) is intended for indoor use only. Environmental exposures are greatly reduced by the fact it cannot be used outdoors (see Document IIA, Section 2.10 for further details). b. Amorphous silicon dioxide as used as an insecticide (PT18) is not intended for direct application to the environment e.g. by spraying, or placement directly onto the ground or soil. Amorphous silicon dioxide as used as an insecticide (PT18) is restricted to use indoors and is for application to cracks and crevices, behind pipes etc. This not only minimises the risk of release directly to the environment, but it also reduces the potential for primary poisoning of non-target species. c. Notwithstanding the above, there is potential for exposure to the environment as a result of disposal of waste material. The risk to the environment from the act of disposal is considered to be insignificant. This is because the quantity of amorphous silicon dioxide being disposed of compared to the volume of total waste is minute. The total estimated disposal of amorphous silicon dioxide across the whole of the EU is < 0.00000073% of the total waste generated and sent to landfill in the UK alone (see Document IIA, Section 2.10 for further details). This means that any amorphous silicon dioxide that is sent for landfill is massively diluted by the large volume of municipal waste continually entering landfill sites in the UK. The data available on the environmental toxicity of amorphous silicon dioxide shows that this volume is extremely unlikely to cause any adverse effect to the environment, and as such requires no further investigation.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.1.4 **Annex Point/TNsG** **Annex IIIA, XII 2.2**	**Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary.** Section 7: Ecotoxicological Profile, including Fate and Behaviour
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FROM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.4.1 Annex Point/TNsG Annex IIIA, XII. 2.1	**Field study on accumulation in the sediment** Section 7: Ecotoxicological Profile including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [✓]	**Technically not feasible** [ ] **Scientifically unjustified** [✓] **Other justification** [ ]	
Detailed justification:	The "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that a field trial on accumulation in the sediment is needed only if non extractable residues are formed in the initial water/sediment study submitted in Document IIIA, section 7.1.2.2.2, and these residues exceed 70% of the initial dose, or if the mineralisation rate in this study is less than 5% in 100 days. An initial water/sediment study has not been submitted in Document IIIA, section 7.1.2.2.2, for the following reasons. 1. The testing of the biodegradation of silicon dioxide in freshwater/sediment is scientifically unjustified because silicon dioxide, under normal conditions of use in Rentokil Initial's insecticide (PT18) products will not be applied directly or indirectly to the sediment in aquatic systems. 2. Testing for the ready biodegradability (A7.1.1.2.1) of silicon dioxide is scientifically unjustified. Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the approved EC method for ready biodegradability (EC method C4 a-f) applies only to organic compounds. In addition, the "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that the ready biodegradation test is required of organic compounds. 3. Inherent biodegradability (A7.1.1.2.2) is technically not feasible to perform on silicon dioxide as the approved EC test methods C9 and C12 are designed to work with water-soluble, non-volatile organic substances. While silicon dioxide is slightly soluble and non-volatile, it is an inorganic compound. It is for the same reasons that it is not necessary to submit a field trial on accumulation of silicon dioxide in the sediment. Notwithstanding this, the preliminary risk assessment for exposure to water does not indicate the need to conduct additional studies on the fate and behaviour of silicon dioxide in the aquatic compartment.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.1.4.1 Annex Point/TNsG Annex IIIA, XII. 2.1	**Field study on accumulation in the sediment** Section 7: Ecotoxicological Profile including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FROM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.1 Annex Point/TNsG Annex IIIA, VII.4, XII.1.1	**Aerobic degradation in soil, initial study** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	It is not scientifically necessary to determine the aerobic biodegradation of silicon dioxide in soil. Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the approved test guideline OECD 304A applies only to ^{14}C-labelled material. It is for this reason that a test to determine the aerobic biodegradation of silicon dioxide in soil has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.2 Annex Point/TNsG Annex IIIA, XII.1.1	**Aerobic degradation in soil, further studies** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓] **Other justification** [ ]	
Detailed justification:	It is not scientifically necessary to determine the aerobic biodegradation of silicon dioxide in soil. Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because biodegradability is relevant only to organic compounds. It is for this reason that tests to determine the aerobic degradation of silicon dioxide in soil have not been submitted. Notwithstanding this, the preliminary risk assessment for exposure to soil does not indicate the need to conduct additional studies on the fate and behaviour of silicon dioxide in the soil compartment.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.2.2 Annex Point/TNsG Annex IIIA, XII.1.1	**Aerobic degradation in soil, further studies** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.2.1 Annex Point/TNsG Annex IIIA, VII.4, XII.1.1, XII.1.4	**The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that the rate and route of degradation including the identification of any metabolites and degradation products in at least three soil types under appropriate conditions is required only if: ▪ The DT_{50lab} determined in the initial aerobic degradation study in soil (Document IIIA, section 7.2.1) is more than 21 days and the PEC/PNEC >1 for soil ▪ there is danger for groundwater ▪ other refinement of the preliminary risk assessment for soil is necessary. An initial aerobic degradation study in soil has not been submitted in Document IIIA, section 7.2.1 for the following reason: Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the approved test guideline OECD 304A applies only to ^{14}C-labelled material. Notwithstanding the above, the preliminary risk assessment for exposure to soil does not indicate the need to conduct studies on the fate and behaviour of silicon dioxide in the soil compartment.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.2.2.1 **Annex Point/TNsG** **Annex IIIA, VII.4, XII.1.1, XII.1.4**	**The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.2.2 **Annex Point/TNsG** **Annex IIIA, XII.1.1,** **Annex VI, para 85**	**Field soil dissipation and accumulation** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that field soil dissipation and accumulation are required in two soil types if : ▪ The $DT_{90field}$ is over one year and ▪ The $DT_{50field}$ is greater than 3 months or ▪ If during laboratory tests non-extractable residues are formed in amounts exceeding 70% of the initial dose after 100 days with a mineralization rate of less than 5% in 100 days. An initial aerobic degradation study in soil has not been submitted in Document IIIA, section 7.2.1 for the following reason: Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the approved test guideline OECD 304A applies only to ^{14}C-labelled material. Notwithstanding the above, the preliminary risk assessment for exposure to soil does not indicate the need to conduct studies on the fate and behaviour of silicon dioxide in the soil compartment, and therefore it is not considered necessary to submit additional data on field soil dissipation and accumulation.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.2.2.2 Annex Point/TNsG Annex IIIA, XII.1.1, Annex VI, para 85	**Field soil dissipation and accumulation** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.2.3 Annex Point/TNsG Annex IIIA, XII.1.4	**Extent and nature of bound residues** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that data on the extent and nature of bound residues on soil are required if: ▪ Data submitted in Document IIIA, section A7.2.1 and A7.2.2.1 indicate that bound residues may be formed which account for more than 10% of the active substance added. An initial aerobic degradation study in soil has not been submitted in Document IIIA, section 7.2.1 for the following reason: Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the approved test guideline OECD 304A applies only to ^{14}C-labelled material. Rate and route of degradation of silicon dioxide in soil was not determined (Document IIIA, section A7.2.2.1) because the preliminary risk assessment for exposure to soil does not indicate the need to conduct studies on the fate and behaviour of silicon dioxide in the soil compartment. The points covered above show that this end point is not relevant for silicon dioxide, on the basis on data submitted in Document IIIA, section A7.2.1 and A7.2.2.1.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.2.2.3 Annex Point/TNsG Annex IIIA, XII.1.4	**Extent and nature of bound residues** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.2.4 Annex Point/TNsG Annex IIIA, XII.1.1	**Other soil degradation studies** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that further soil degradation studies are required for different release conditions. The preliminary risk assessment for exposure to soil does not indicate the need to conduct studies on the fate and behaviour of silicon dioxide in the soil compartment, and therefore it is not considered necessary to submit additional data on release to soil under different release conditions.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.2.2.4 Annex Point/TNsG Annex IIIA, XII.1.1	**Other soil degradation studies** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.3 Annex Point/TNsG Annex IIIA, XII.1.2-1.3	**Adsorption and mobility in soil, further studies** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that further adsorption and mobility studies are required to determine adsorption and desorption in soil under environmentally relevant conditions. The preliminary risk assessment for exposure to soil does not indicate the need to conduct studies on the fate and behaviour of silicon dioxide in the soil compartment, and therefore it is not considered necessary to submit additional data on adsorption and mobility studies in soil.	
Undertaking of intended data submission [ ]	Not applicable.	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.3.1 **Annex Point/TNsG** **Annex IIIA, XII.1.2**	**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption metabolites and degradation products** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [✓]	**Other justification** [ ]	
Detailed justification:	The "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that adsorption and desorption in at least three soil types is required if: ▪ Screening tests on the adsorption/desorption of metabolites and other degradation products are required for compounds which at any sampling time during the soil degradation studies account for more than 10% of the active substance added. ▪ A full scale adsorption test is required if a substance is used directly on, released to or disposed on/in soil in relevant amounts, unless the substance is shown to be readily biodegradable. ▪ A full scale adsorption test may be required to refine the PEC value if the PEC/PNEC ratio is >1, or relevant concentrations of the substance reaches groundwater. It is not considered necessary to conduct an adsorption/desorption test for silicon dioxide in three soil types, for the following reasons: 1. Silicon dioxide, under normal conditions of use in Rentokil Initial's insecticide (PT18) products, will not be applied directly on soil or released to soil in relevant concentrations. 2. The preliminary risk assessment for exposure to soil does not indicate the need to conduct studies on the fate and behaviour of silicon dioxide in the soil compartment, and therefore it is not considered necessary to submit additional data on adsorption and mobility studies in soil.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.2.3.1 **Annex Point/TNsG** **Annex IIIA, XII.1.2**	**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption metabolites and degradation products** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.3.2 Annex Point/TNsG Annex IIIA, XII.1.3	**Mobility in at least three soil types and where relevant mobility of metabolites and degradation products** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [✓]	**Other justification** [ ]	
Detailed justification:	The "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that a study to determine mobility of a substance in soil is required if it is indicated from data on adsorption and degradation in soil that relevant amounts of the substance may reach ground water. The preliminary risk assessment for exposure to soil does not indicate the need to conduct studies on the fate and behaviour of silicon dioxide in the soil compartment, and therefore it is not considered necessary to submit additional data on mobility of silicon dioxide in soil.	
Undertaking of intended data submission [ ]	Not applicable.	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.3.1 Annex Point/TNsG Annex IIIA, VII 5	**Phototransformation in air (estimation method), including identification of breakdown products** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	It is not considered to be scientifically necessary to determine the phototransformation of silicon dioxide in air because it is not volatile, and therefore exposure via the atmospheric compartment is not considered relevant. Notwithstanding the above, the structure of silicon dioxide is O=Si=O. This structure means that OH-radicals are unlikely to be generated during degradation in air. When pseudo-first order rate constant for degradation in air was estimated using the QSAR method [1], the rate constant was zero. This result supports the above statement that OH radicals are unlikely to be generated during degradation of silicon dioxide in air. For the evaluation of atmospheric risk, the following abiotic effects of a chemical on the atmosphere have to be considered: global warming, ozone depletion in the stratosphere, ozone formation in the troposphere, and acidification. This is in accordance with EC 1996 (Technical Guidance Document in support of Commission Directive 93.67/EEC on risk assessment for new notified substances and Commission Regulation EC No 1488/94 on risk assessment for existing substances. Part II Environmental risk assessment). Silicon dioxide will not have an impact on global warming because it does not exist in the gaseous state at ambient temperature and pressure. The presence of absorption bands in the IR spectrum region 800-1200nm is therefore not applicable. It is also highly unlikely that silicon dioxide will have any impact either on ozone depletion in the stratosphere or ozone formation in the troposphere. This is because silicon dioxide does not contain chlorine substituents, and OH radicals are unlikely to be generated during degradation of silicon dioxide in air. The final atmospheric risk indicator is acidification. During the oxidation of substances containing Cl, F, N or S substituents, acidifying components (e.g. HCl, HF, NO_2, SO_2 and H_2SO_4) may be formed. As silicon dioxide does not contain Cl, F, N or S substituents, acidification is not considered to be a risk to receiving soil or surface water. [redacted]	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.3.1 Annex Point/TNsG Annex IIIA, VII 5	**Phototransformation in air (estimation method), including identification of breakdown products** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FROM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.3.2 Annex Point/TNsG Annex IIIA, XII.3	**Fate and behaviour in air, further studies** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that further studies are required to determine fate and behaviour in air if : ▪ The active substance is to be used in fumigant preparations ▪ The active substance causes risk to the atmospheric compartment Silicon dioxide is not intended for use as a fumigant. As shown in Document IIIA, section 7.3.1 the preliminary risk assessment for exposure to the atmosphere does not indicate the requirement for additional studies. It is for these reasons that no further studies to determine fate and behaviour of silicon dioxide in the air have been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.3.2 Annex Point/TNsG Annex IIIA, XII.3	**Fate and behaviour in air, further studies** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS FORM OTHER MEMBER STATES *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

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		1 REFERENCE
1.1	**Reference**	[redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Rentokil Initial plc, Felcourt, East Grinstead, West Sussex United Kingdom RH19 2JY
1.2.2		
1.2.3	Criteria for data protection	Data submitted to MS after 13 May 2000 on existing active substance for the purpose of its entry into Annex I.
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes. OECD Guidelines for Testing of Chemicals. Method 203. Fish, Acute Toxicity Test. Adopted 17 July 1992.
2.2	**GLP**	Yes
2.3	**Deviations**	No.
		3 MATERIALS AND METHODS
3.1	**Test material**	As given in section 2
3.1.1	Lot/Batch number	GA5007
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	Not applicable. Biocidal product not used.
3.1.5	Further relevant properties	Solubility of test substance: 112.739 g/L
3.1.6	Method of analysis	Please refer to method of analysis for amorphous silicon dioxide in Trout Media in Document IIIA, Section 4.2 (e).
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Not applicable.
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	Not applicable. No reference substance used.
3.4	**Testing procedure**	*Non-entry field*
3.4.1	Dilution water	See table A7_4_1_1-1
3.4.2	Test organisms	See table A7_4_1_1-2

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

3.4.3	Test system	See table A7_4_1_1-3
3.4.4	Test conditions	See table A7_4_1_1-4
3.4.5	Duration of the test	96 hours
3.4.6	Test parameter	Mortality
3.4.7	Sampling	Samples were taken from the centre of the test solutions at 0 and 96 hours, stored for a maximum of 8 days and sent for analysis at [redacted] The concentrations of silicon in the test solutions were determined by ICP-AES. In order to express results in terms of amorphous silicon dioxide, results were converted from measured silicon (Si) to silicon dioxide (SiO_2) by multiplying by 60/28.
3.4.8	Monitoring of TS concentration	No
3.4.9	Statistics	Not applicable. No mortality recorded.
		4 RESULTS
		If appropriate, include tables. Sample tables are given below
4.1	**Limit Test**	Performed
4.1.1	Concentration	110 mg/L
4.1.2	Number/ percentage of animals showing adverse effects	0
4.1.3	Nature of adverse effects	No adverse effetcs shown.
4.2	**Results test substance**	*Non-entry field*
4.2.1	Initial concentrations of test substance	See Table A7_4_1_1-5
4.2.2	Actual concentrations of test substance	See Table A7_4_1_1-5
4.2.3	Effect data (Mortality)	See tables A7_4_1_1-6 and A7_4_1_1-7
4.2.4	Concentration / response curve	Not applicable. No mortality recorded.
4.2.5	Other effects	No general symptoms of toxicity were noted in this study.
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	See Table A7_4_1_1-8
4.3.2	Nature of adverse	None.

effects

4.4	**Test with reference substance**	Not performed
4.4.1	Concentrations	Not applicable.
4.4.2	Results	Not applicable.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Study was performed in accordance with OECD Test Guideline 203, Fish, Acute Toxicity Test. Adopted 17 July 1992.

Test procedure and apparatus

The test procedure employed was a static system. Single borosilicate glass vessels (external dimensions; 460 mm × 305 mm × 310 mm; length × width × height) were used for the dilution water control and the exposure solution. The vessels had a working volume of 25 L.

The test was undertaken in a temperature controlled room which was set at the nominal test temperature of 15 ± 1°C. The test solutions were gently aerated.

The photoperiod in this study was 16 hours fluorescent light and 8 hours dark with 20 minute dawn and dusk transition periods commencing at 06:00 and 21:40 hours.

At the start of the test ten fish were randomly allocated to the single test concentration and the dilution water control. The fish were not fed during the course of the test.

Preparation of test solutions

The test substance was synthetic amorphous silica (silicon dioxide) with an expected water solubility of 112 mg/L after 5 days at 30°C (Information provided by the Sponsor). In order to test at the limit of solubility, the procedure described below was used to prepare a nominal loading rate of 110 mg/L, together with a dilution water control.

The test concentration was prepared by the addition of an appropriate quantity of test substance directly to approximately 35 litres of dilution water in a tank containing an aquarium heater set at 30°C. The mixture was stirred at a level sufficient to create a small vortex for at least 5 days at 30°C. The resultant solution was a slightly cloudy homogeneous suspension.

After at least 5 days the test solution was allowed to settle and cool to the test temperature over 24 hours. Using glassware and minimal silicon tubing the solution was passed through a 0.45 µm nylon filter using a Watson Marlow peristaltic pump. Approximately 25 litres of the collected supernatant was dispensed to the test vessel. The final solution was clear and colourless.

The control consisted of dilution water only and was treated in the same manner as the test solution.

Analytical method

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

Samples were taken from the centre of the test solutions at 0 and 96 hours, stored for a maximum of 8 days and sent for analysis at [redacted] Analysis was conducted in accordance with Good Laboratory Practice (GLP). All reports are archived at [redacted]

The concentrations of silicon in the test solutions were determined by ICP-AES. In order to express results in terms of test substance, results were converted from measured silicon (Si) to silicon dioxide (SiO_2) by multiplying by 60/28.

Observations for mortality and symptoms of toxicity

Observations for mortalities and symptoms of toxicity were made at 3, 24, 48, 72 and 96 hours.

Physical and chemical parameters

Daily measurements of the test solutions were undertaken throughout the 96 hour period for pH and dissolved oxygen concentration using calibrated meters. Temperature values were determined daily using a mercury-in-glass thermometer calibrated to 0.1°C and conforming to BS593. Hourly temperature measurements were also recorded automatically in the dilution water control using an electronic recording system.

5.2 Results and discussion

Analytical data

The concentrations of amorphous silicon dioxide determined in the exposure solutions are given in Table A7_4_1_1-5. All analytical values are quoted to two significant figures and percentages to the nearest integer. The mean measured concentration of silicon dioxide in the exposure concentration was 109% of the nominal value. A mean measured concentration equivalent to 6.7 mg/L of silicon dioxide was determined in the dilution water control. This is not considered to be test substance as measured levels of silicon were similar to background levels in fresh dechlorinated water (2.5 mg/L silicon, equivalent to 5.3 mg/L silicon dioxide)

On the basis of the analytical data the nominal concentration was used for the calculation and reporting of the results.

Biological data

Observations of mortalities are shown in Table A7_4_1_1-6. The LC_{50} is defined as the concentration, calculated from the data obtained, resulting in the death of 50% of the fish in the time period specified.

No general symptoms of toxicity were noted in this study.

The results obtained (based on the nominal concentration of amorphous silicon dioxide) were:

The NOEC (no observed effect concentration) is defined as the highest tested loading rate in which there were no mortalities or symptoms of toxicity within the period of the test, therefore,

96 hour NOEC = 110 mg/L

The lowest nominal concentration at which there was 100% mortality was >110 mg/L. There were no mortalities in the dilution water control.

Physical and chemical data

The dissolved oxygen concentrations in the test vessels ranged from 9.4 to 9.9 mg/L, pH values ranged from 7.5 to 7.9, and the temperatures

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

		recorded were within the range 15 ± 1°C. Daily dissolved oxygen, pH and temperature measurements are shown in Tables 3 and 4. At no time during the course of the study was dissolved oxygen concentration in any of the test vessels less than 60% of the air-saturation value (6.1 mg/L). The continuous record of temperature, recorded automatically, in the dilution water control during the study remained within 15 ± 1°C. The total hardness of the dilution water was 46.7 mg/L $CaCO_3$, and the conductivity of the water was 246 µS/cm at 25°C. Full water quality parameters of the dechlorinated water supply are shown in Table A7_4_1_1-1.
5.2.1	LC_0	Not reported.
5.2.2	LC_{50}	96 h : >110 mg/L
5.2.3	LC_{100}	No reported.
5.3	**Conclusion**	The validity criteria for this test have been fulfilled (see validity criteria summarized in table table A7_4_1_1-9). The nominal, maximum possible dose of test substance used produced no adverse effects in the test organisms.
5.3.1	Other Conclusions	96 h NOEC = 110 mg/L
5.3.2	Reliability	1
5.3.3	Deficiencies	No

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and Methods	*State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_4_1_1-1: Dilution water

Criteria	Details
Source	Dechlorinated tap water.
Alkalinity	28.8 mg $CaCO_3$ /L
Hardness	Total $CaCO_3$ 46.7 mg/L
pH	7.5
Oxygen content	Not reported
Conductance	246 µS/cm at 25°C
Holding water different from dilution water	Yes. Stock fish were held in 25% seawater, as a prophylactic, between 27 July and 2 September 2005. Prior to the test the fish were acclimatised to the test temperature (15 ± 1°C) for a minimum period of 7 days.

Table A7_4_1_1-2: Test organisms

Criteria	Details
Species/strain	*Oncorhynchus mykiss*
Source	The fish (batch 32/05) were obtained from Houghton Springs Fish Farm, Winterbourne Houghton, Blandford Forum, Dorset DT11 0PD.
Wild caught	No
Age/size	The range in weight was 1.21 to 2.35 g with a mean of 1.92 g, and the range in length was 44 to 53 mm with a mean of 50 mm.
Kind of food	During the holding and acclimatisation periods the fish were fed appropriate amounts of a commercial fish food.
Amount of food	During the holding and acclimatisation periods the fish were fed appropriate amounts of a commercial fish food.
Feeding frequency	Not specified in report.
Pretreatment	Prior to the test the fish were acclimatised to the test temperature (15 ± 1°C) for a minimum period of 7 days.
Feeding of animals during test	No. Food was withheld from the fish for at least 24 hours prior to the commencement of the test.

Table A7_4_1_1-3: Test system

Criteria	Details
Test type	Static
Renewal of test solution	Not applicable.
Volume of test vessels	Single borosilicate glass vessels (external dimensions; 460 mm × 305 mm × 310 mm; length × width × height). The vessels had a working volume of 25 l.
Volume/animal	The loading of fish in the dilution water control was approximately 0.77 g l^{-1}.
Number of animals/vessel	10
Number of vessels/ concentration	1
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_1-4: Test conditions

Criteria	Details									
Test temperature	Nominal loading rate of amorphous silicon dioxide (mg/L)	Temp (°C)								
		0 hour		24 hour		48 hour		72 hour		96 hour	
	Dilution water control	15.6		15.2		15.0		15.0		15.1	
	110	15.5		15.1		14.		15.0		15.0	
Dissolved oxygen	Nominal loading rate of amorphous silicon dioxide	0 hour		24 hour		48 hour		72 hour		96 hour	
	(mg/L)	DO (mg/L)	DO[a] (%)	DO (mg/L)	DO[a] (%)	DO (mg/L)	DO[a] (%)	DO (mg/L)	DO[a] (%)	DO (mg/L)	DO[a] (%)
	Dilution water control	9.8	97	9.7	96	9.8	97	9.9	98	9.8	97
	110	9.4	93	9.8	97	9.6	95	9.7	96	9.7	96
pH	Nominal loading rate of amorphous silicon dioxide (mg/L)	pH									
		0 hour		24 hour		48 hour		72 hour		96 hour	
	Dilution water control	7.7		7.6		7.5		7.5		7.6	
	110	7.9		7.5		7.5		7.5		7.5	
Adjustment of pH	No										
Aeration of dilution water	Yes. Gentle.										
Intensity of irradiation	Not reported.										
Photoperiod	The photoperiod in this study was 16 hours fluorescent light and 8 hours dark with 20 minute dawn and dusk transition periods commencing at 06:00 and 21:40 hours.										

DO = Dissolved oxygen

a Quoted as percentage of the 100% air saturation value of 10.1 mg/Lat 15°C

Table A7_4_1_1-5: Analytical Results[a]

Nominal loading rate of amorphous silicon dioxide	0 hours		96 hours		Mean measured conc of silicon dioxide over the test duration[b]	Mean measured conc as % of
(mg/L)	Measured conc. of silicon (mg/L)	Silicon dioxide equivalent (mg/L)	Measured conc. of silicon (mg/L)	Silicon dioxide equivalent (mg/L)	(mg l^{-1})	nominal
Dilution water control	3.1	6.6	3.1	6.6	-[b]	-
110	56[d]	120	57[e]	120	120 [c]	109

[a] All measurements are quoted to 2 significant figures and percentages are quoted to the nearest integer. Results were converted from measured silicon (Si) to silicon dioxide (SiO_2) by multiplying by 60/28

[b] Not considered to be test substance, measured levels of silicon were similar to background levels in fresh dechlorinated water (2.5 mg/L silicon, equivalent to 5.3 mg/L silicon dioxide)

[c] Calculated using the arithmetic mean of the 0 and 96 hour silicon dioxide results

[d] Mean of triplicate analyses: 56, 56, 57 mg/L

[e] Mean of triplicate analyses: 57, 56, 57 mg/L

Table A7_4_1_1-6: Mortality data (Test substance)

Test-Substance Concentration (nominal) [mg/L]	**Mortality**							
	Number				**Percentage**			
	24 h	**48 h**	**72 h**	**96 h**	**24 h**	**48 h**	**72 h**	**96 h**
110	0	0	0	0	0	0	0	0
Temperature [°C]	15.1	14.9	15.0	15.0				
pH	7.5	7.5	7.5	7.5				
Oxygen [mg/L]	9.8	9.6	9.7	9.7				

Table A7_4_1_1-7: Effect data

	24 h [mg/l]	**95 % c.l.**	**48 h [mg/l]**	**95 % c.l.**	**72 h [mg/l]**	**95 % c.l.**	**96 h [mg/l]**	**95 % c.l.**
LC_0	Not reported.	Not reported.	Not reported.	Not reported.	Not reported.	Not reported.	Not reported.	Not reported.
LC_{50}	>110 (n)	Not reported.	>110 (n)	Not reported.	>110 (n)	Not reported.	>110 (n)	Not reported.
LC_{100}	Not reported.	Not reported.	Not reported.	Not reported.	Not reported.	Not reported.	Not reported.	Not reported.

Table A7_4_1_1-8: Mortality data (Controls)

Test-Substance Concentration (nominal) [mg/L]	Mortality							
	Number				Percentage			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
110	0	0	0	0	0	0	0	0
Temperature [°C]	15.2	15.0	15.0	15.1				
pH	7.6	7.5	7.5	7.6				
Oxygen [mg/L]	9.7	9.8	9.9	9.8				

Table A7_4_1_1-9: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	Not fullfilled
Mortality of control animals <10%	4	
Concentration of dissolved oxygen in all test vessels > 60% saturation	4	
Concentration of test substance ≥80% of initial concentration during test	4	

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

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	1 REFERENCE	
1.1	**Reference**	[redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Rentokil Initial plc, Felcourt, East Grinstead, West Sussex United Kingdom RH19 2JY
1.2.2		
1.2.3	Criteria for data protection	Data submitted to MS after 13 May 2000 on existing active substance for the purpose of its entry into Annex I.
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes. OECD Guidelines for the Testing of Chemicals. Test Guideline 202 Part I, *Daphnia sp.*, Acute Immobilisation Test. Adopted 4 April 1984.
2.2	**GLP**	Yes
2.3	**Deviations**	No.
	3 MATERIALS AND METHODS	
3.1	**Test material**	As given in section 2
3.1.1	Lot/Batch number	GA5007
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	Not applicable. Biocidal product not used.
3.1.5	Further relevant properties	Solubility of test substance: 112.739 g/L
3.1.6	Method of analysis	Please refer to method of analysis for amorphous silicon dioxide in Daphnia Media in Document IIIA, Section 4.2 (f).
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Not applicable.
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	Not applicable.
3.4	**Testing procedure**	*Non-entry field*
3.4.1	Dilution water	See table A7_4_1_2-1

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

3.4.2	Test organisms	See table A7_4_1_2-2
3.4.3	Test system	See table A7_4_1_2-3
3.4.4	Test conditions	See table A7_4_1_2-4
3.4.5	Duration of the test	48 hours
3.4.6	Test parameter	Immobility
3.4.7	Sampling	Samples were taken from the centre of the test solutions at 0 and 48 hours, stored for a maximum of 10 days and sent for analysis at [redacted] Analysis was conducted in accordance with Good Laboratory Practice (GLP). All reports are archived at [redacted]
3.4.8	Monitoring of TS concentration	No
3.4.9	Statistics	Not applicable. No immobilisation recorded.
		4 RESULTS
4.1	**Limit Test**	Performed
4.1.1	Concentration	86 mg/L
4.1.2	Number/ percentage of animals showing adverse effects	0
4.1.3	Nature of adverse effects	None.
4.2	**Results test substance**	*Non-entry field*
4.2.1	Initial concentrations of test substance	86 mg/L
4.2.2	Actual concentrations of test substance	See Table A7_4_1_2-5
4.2.3	Effect data (Immobilisation)	48 h NOEC = 86 mg/L. See Table A7_4_1_2-6 and Table A7_4_1_2-7 for data.
4.2.4	Concentration / response curve	Not applicable. No immobilisation recorded.
4.2.5	Other effects	None.
4.3	**Results of controls**	See Table A7_4_1_2-7
4.4	**Test with reference substance**	Not performed.
4.4.1	Concentrations	Not applicable.
4.4.2	Results	Not applicable.

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Study was performed in accordance with OECD Guidelines for the Testing of Chemicals. Test Guideline 202 Part I, *Daphnia sp.*, Acute Immobilisation Test. Adopted 4 April 1984.

Test procedure and apparatus

Borosilicate glass beakers of 250 ml nominal capacity were used as test vessels, with four replicates for the dilution water control and exposure solution. Each vessel contained 200 ml of test solution providing a depth of approximately 60 mm. The beakers were covered with loose fitting glass lids. The positions of the treatments were randomly allocated within the test area.

The test was initiated by the addition of five randomly selected *Daphnia*, in <2.0 ml of dilution water, to each test vessel. The dilution water control and exposure solution contained a total of 20 *Daphnia*. The loading of the *Daphnia* in each test vessel was 25 *Daphnia*/L.

The nominal test solution temperature was 20 ± 1°C, maintained by control of the room temperature. A photoperiod of 16 hours light:8 hours dark, with 20 minute dusk and dawn transition periods, was provided. The test solutions were not aerated and the *Daphnia* were not fed during the course of the study.

Preparation of test solutions

The test substance was synthetic amorphous silica (silicon dioxide) with an expected water solubility of 112 mg/L after 5 days at 30°C. In order to test at the limit of solubility, the procedure described below was used to prepare a nominal loading rate of 110 mg/L, together with a dilution water control.

The test concentration was prepared by the addition of an appropriate quantity of test substance directly to 1 litre of dilution water in a volumetric flask. The flask was placed into a waterbath set at 30°C and stirred at a level sufficient to create a small vortex for at least 5 days at 30°C. The resultant solution contained very fine particulates.

After at least 5 days the test solution was allowed to settle and cool to the test temperature over 24 hours. Using glassware and minimal silicon tubing the solution was passed through a 0.45 µm nylon filter using a Watson Marlow peristaltic pump. Approximately 100 ml was filtered to waste then 60 ml of the collected supernatant was dispensed to each test vessel. The final solution was clear and colourless.

The control consisted of dilution water only and was treated in the same manner as the test solution. In both cases, the final solutions contained nutrients as specified in Table A7_4_1_2-8.

Observation of effects

An assessment of the response of the *Daphnia* was made 24 and 48 hours after the commencement of the test. Each *Daphnia* was viewed by eye and was defined as affected if showing no whole body movement, relative to the water, within a period of 15 seconds even if movement of individual appendages was visible. *Daphnia* so affected

were termed immobile.

The median effect concentration (EC_{50}) was defined as the concentration resulting in 50% immobilisation of the *Daphnia* in the time period specified.

The numbers of *Daphnia* immobilised in the replicates of the dilution water control and each test concentration were summed for each time period.

Physical and chemical parameters

The total hardness of the reconstituted dilution water was measured (as mg/L $CaCO_3$) before the start of the test.

Measurements were undertaken at the beginning and end of the test for pH and dissolved oxygen concentration using calibrated meters. The initial pH and dissolved oxygen concentration of the dilution water control and test solution were measured using the excess remaining after filling the test vessels. At the end of the study, the pH and dissolved oxygen concentration of two replicates of the dilution water control and test concentration were measured.

Temperature values were determined daily using a mercury-in-glass thermometer calibrated to BS593. Hourly measurements were also recorded automatically in the additional dilution water control test vessel using a calibrated electronic recording system.

5.2 Results and discussion

Highest achievable dilution of amorphous silicon dioxide was used in the tests.

Analytical data

The concentrations of test substance determined in the exposure solutions are given in Table A7_4_1_2-5. All analytical values are quoted to two significant figures and percentages to the nearest integer. The mean measured concentration of silicon dioxide in the exposure concentration was 78% of the nominal value. A mean measured concentration equivalent to 0.74 mg/L of silicon dioxide was determined in the dilution water control. Although this is higher than background levels in fresh *Daphnia* medium (0.14 mg/L silicon, equivalent to 0.31 mg/L silicon dioxide) it is considered unlikely to be the test substance.

On the basis of the analytical data the mean measured concentration was used for the calculation and reporting of the results.

Biological data

The numbers of Daphnia immobilised after 24 and 48 hours are given in Table A7_4_1_2-6.

The results obtained (based on mean measured concentration of test substance) were:

Time	EC_{50}
24 hour	>86 mg/L
48 hour	>86 mg/L

The NOEC (no observed effect concentration) is defined as the highest tested concentration in which there was no immobilisation of the *Daphnia* within the period of the test, therefore,

Section A7.4.1.2 **Acute toxicity to invertebrates**

Annex Point IIA7.2 *Daphnia magna*

		48 hour NOEC = 86 mg/L The lowest mean measured concentration at which there was 100% immobilisation was >86 mg/L. There was no immobility observed in the dilution water control. No symptoms of toxicity were observed in this study. **Physical and chemical data** Dissolved oxygen concentrations ranged from 8.2 to 9.0 mg/L and the pH values ranged from 7.9 to 8.3. Individual data are shown in Table A7_4_1_2-4. At the end of the study the dissolved oxygen concentration in the dilution water control and highest test concentration was ≥3 mg/L, the minimum recommended in the OECD Guideline. The thermometer readings at 0, 24 and 48 hours were 20.4, 20.4 and 20.5°C. The continuous temperature recorded automatically over the 48 hours remained within 20 ± 1°C. The total hardness of the Daphnia media was 208 mg/L $CaCO_3$, and the conductivity of the water was 583 µS/cm. Water quality parameters of the Daphnia media used in this study are shown in Table A7_4_1_2-8.
5.2.1	EC_0	Not reported.
5.2.2	EC_{50}	>86 mg/L
5.2.3	EC_{100}	Not reported.
5.3	**Conclusion**	Validity criteria for this study have been fulfilled (see validity criteria summarized in Table A7_4_1_2-9). No adverse effects were shown at the maximum attainable level of test substance.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and Methods	*State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	