Table A7_4_1_2-1: Dilution water

Criteria	Details
Source	Elendt's M4 *Daphnia* medium
Alkalinity	38.8 mg $CaCO_3$/L
Hardness	$CaCO_3$: 208.3 mg/L
pH	8.1
Ca / Mg ratio	Not reported.
Na / K ratio	Not reported.
Oxygen content	Chemical oxygen demand : <12.0
Conductance	583 µS/cm at 25°C
Holding water different from dilution water	No

Table A7_4_1_2-2: Test organisms

Criteria	Details
Strain	*Daphnia magna*
Source	The culture was originally obtained from IRCHA, France and the *Daphnia* were subsequently characterised by Sheffield University, UK as Clone 5.
Age	<24 hours old
Breeding method	Diploid parthenogenesis
Kind of food	*Chlorella vulgaris*, strain CCAP 211/12 and commercially available fish food.
Amount of food	Not reported.
Feeding frequency	Not reported.
Pretreatment	Holding conditions identical to test conditions.
Feeding of animals during test	No

Table A7_4_1_2-3: Test system

Criteria	Details
Renewal of test solution	Not applicable.
Volume of test vessels	250 mL
Volume/animal	50 mL
Number of animals/vessel	25 *Daphnia*/L
Number of vessels/ concentration	4
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_2-4: Test conditions

Criteria	Details			
Test temperature	0 hours: 20.4°C; 24 hours: 20.4°C; 48 hours: 20.5°C			
Dissolved oxygen	Nominal loading rate of amorphous silicon dioxide	Dissolved oxygen conc.		
		0 hour (mg/L)	48 hour (mg/L)	
			Rep C	Rep D
	Dilution water control	9.0	8.6	8.2
	110	8.4	8.2	8.2

pH	Nominal loading rate of amorphous silicon dioxide	Dissolved oxygen conc.		
		0 hour	48 hour	
			Rep C	Rep D
	Dilution water control	8.3	8.1	8.1
	110	7.9	8.0	8.0

Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	Not reported.
Photoperiod	A photoperiod of 16 hours light: 8 hours dark, with 20 minute dusk and dawn transition periods was provided.

Table A7_4_1_2-5: Analytical Results[a]

Nominal loading rate of Gasil 23D (mg/L)	0 hours		96 hours		Mean measured conc of silicon dioxide over the test duration (mg/L)	Mean measured conc as % of nominal
	Measured conc. of silicon (mg/L)	Silicon dioxide equivalent (mg/L)	Measured conc. of silicon (mg/L)	Silicon dioxide equivalent (mg/L)		
Dilution water control	0.34[c]	0.73	0.35[c]	0.75	-[b]	-
110	40[d]	86	40[e]	86	86[c]	78

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 Although the level of silicon is higher than background levels in fresh *Daphnia* medium (0.14 mg/L silicon, equivalent to 0.31 mg/L silicon dioxide), considered unlikely to be test substance

c Calculated using the arithmetic mean of the 0 and 48 hour silicon dioxide results

d Mean of triplicate analyses: 41, 40, 40 mg/L

e Mean of triplicate analyses: 40, 40, 39 mg/L

Analysis conducted at [redacted] in accordance with Good Laboratory Practice (GLP). All reports archived at [redacted]

[redacted]

Table A7_4_1_2-6: Immobilisation data

Test-Substance Concentration (effective) [mg/L]	Replicate	Immobile *Daphnia*						
		Number		Percentage		Oxygen [mg/L]	pH	Temperature [°C]
		24 h	48 h	24 h	48 h	48 h	48 h	48 h
86	A	0	0	0	0	-	-	20.5°C
86	B	0	0	0	0	-	-	20.5°C
86	C	0	0	0	0	8.2	8.0	20.5°C
86	D	0	0	0	0	8.2	8.0	20.5°C
Dilution water control	A	0	0	0	0	-	-	20.5°C
Dilution water control	B	0	0	0	0	-	-	20.5°C
Dilution water control	C	0	0	0	0	8.6	8.1	20.5°C
Dilution water control	D	0	0	0	0	8.2	8.1	20.5°C

Table A7_4_1_2-7: Effect data

	EC_{50}	95 % c.l.	EC_0	EC_{100}
24 h [mg/L]	>86 (m)	Not reported.	Not reported.	Not reported.
48 h [mg/L]	>86 (m)	Not reported.	Not reported.	Not reported.

Table A7_4_1_2-8: Dilution/Reconstituted Water Parameters

Parameter	Dilution water batch used in study (batch number: M42005-19)
pH	8.1
Conductivity @ 25°C	583 µS/cm
Total hardness as $CaCO_3$	208.3 mg/L
Alkalinity as $CaCO_3$	38.8 mg/L
Total suspended solids[a]	<3.0 mg/L
Dissolved organic carbon[a]	0.85 mg/L
Total ammonia as NH_3-N[a]	<30.0 µg/L
Chemical oxygen demand[a]	<12.0
Highest organophosphorous pesticides[a]	<0.005 µg/L
Highest organochlorine pesticides[a]	<0.029 µg/L
Highest PCB[a]	<0.001 µg/L
Aluminium[a]	<4.0 µg/L
Arsenic[a]	<1.0 µg/L
Boron[a]	619 µg/L
Cadmium[a]	<0.10 µg/L
Chromium[a]	<0.50 µg/L
Cobalt[a]	2.420 µg/L
Copper[a]	6.750 µg/L
Iron[a]	155 µg/L
Lead[a]	<2.0 µg/L
Manganese[a]	98.90 µg/L
Mercury[a]	<0.008 µg/L
Nickel[a]	<3.0 µg/L
Silver[a]	<1.0 µg/L
Zinc[a]	9.250 µg/L

[a] Analysis conducted at [redacted] All reports archived at [redacted]

Table A7_4_1_2-9: Validity criteria for acute daphnia immobilistaion test according to OECD Guideline 202

	fulfilled	Not fullfilled
Immobilisation of control animals <10%	4	
Control animals not staying at the surface	4	
Concentration of dissolved oxygen in all test vessels >3 mg/l	4	
Concentration of test substance ≥80% of initial concentration during test	4	

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3

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 Testing of Chemicals. Test Guideline 201. Alga, Growth Inhibition Test. Adopted 7 June 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 Algal Media in Document IIIA, Section 4.2 (6).
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	Culture medium	Medium was made as described below: 1. To approximately 900 ml of distilled water add 1 ml of solutions A1,

A2, A3 and B. 2. Make up to 1 litre with distilled water. 3. Autoclave at 121°C (103 kPa) for 15 minutes, allow to cool. (This procedure causes a slight volume loss through the evaporation of distilled water which is replaced by sterile addition). 4. Add 1 ml of solution C (aseptic technique). 5. Store all solutions under refrigeration.

Solution A1

$NaNO_3$	12.75 g
$MgCl_2.6H_2O$	6.082 g
$CaCl_2.2H_2O$	2.205 g
Distilled H_2O	to 500 ml

Solution A2

$MgSO_4.7H_2O$	7.35 g
Distilled H_2O	to 500 ml

Solution A3

$K_2HPO_4.3H_2O$	0.684 g
Distilled H_2O	to 500 ml

Solution B (Micronutrients)

H_3BO_3	0.093 g
$MnCl_2.4H_2O$	0.208 g
$FeCl_3.6H_2O$	0.080 g
$Na_2EDTA.2H_2O$	0.150 g
$ZnCl_2$	1.64 mg
$CoCl_2.6H_2O$	0.714 mg
$Na_2MoO_4.2H_2O$	3.63 mg
$CuCl_2.2H_2O$	0.006 mg
Distilled H_2O	to 500 ml

Solution C

$NaHCO_3$	7.50 g
Distilled H_2O	to 500 ml

(Filter sterilise into sterile vessel)

Note: All weights and volumes described are nominal values

3.4.2	Test organisms	See Table A7_4_1_3-1
3.4.3	Test system	See Table A7_4_1_3-2
3.4.4	Test conditions	See table A7_4_1_3-3
3.4.5	Duration of the test	72 hours
3.4.6	Test parameter	Cell growth rates
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	Yes. See table A7_4_1_3-4
3.4.9	Statistics	The area under the growth curve, 0 to 72 hours (0 to 3 days) was calculated for each replicate culture, according to the formula given in the OECD Guideline.
		4 RESULTS
4.1	**Limit Test**	Performed
4.1.1	Concentration	54 mg/L (highest attainable concnetration)
4.1.2	Number/ percentage of animals showing adverse effects	See table A7_4_1_3-5
4.2	**Results test substance**	*Non-entry field*
4.2.1	Initial concentrations of test substance	54 mg/L
4.2.2	Actual concentrations of test substance	54 mg/L
4.2.3	Growth curves	See Fig. 1
4.2.4	Concentration / response curve	Not applicable. No growth inhibition recorded.
4.2.5	Cell concentration data	See table A7_4_1_3-5
4.2.6	Effect data (cell multiplication inhibition)	No observed effect concentration (NOEC)= 54 mg/L Lowest observed effect concentration (LOEC) > 54 mg/L Median effective concentration, biomass (E_bC50) > 54 mg/L
4.2.7	Other observed effects	Indicate e.g. any observed inhibition phenomena
4.3	**Results of controls**	See table A7_4_1_3-5
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 Guidelines for Testing of Chemicals. Test Guideline 201. Alga, Growth Inhibition Test. Adopted 7 June 1984. **Test procedure and apparatus**

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3

The test vessels were borosilicate glass conical flasks of 250 ml nominal capacity closed with polyurethane foam bungs. Each flask contained 100 ml of test solution. The cultures were incubated at 24 ± 2°C (the nominal test temperature), under continuous "cool-white" illumination, with orbital shaking at 160 rpm, in a Gallenkamp type INR-401 orbital incubator.

Six replicate cultures of the culture medium control and single concentration of test substance were employed. The positions of the test vessels in the incubator were randomised by rows, and re-randomised daily. One blank vessel (without algal inoculum) for the culture medium control and each test concentration was incubated concurrently.

The algal cell densities of the inoculum and test cultures were determined by electronic particle counting, using a Coulter counter model Z1, counting at a lower threshold equivalent spherical diameter of approximately 2.3 µm. Each replicate test vessel was inoculated with 0.79 ml of the inoculum culture to give a nominal cell density of 1.00×10^4 cells/mL. Three 100 ml volumes of Coulter electrolyte, inoculated in the same manner, had a mean measured cell density of 1.01×10^4 cells/mL. The latter value was used for growth calculations.

After 24, 48 and 72 hours, (1, 2 and 3 days) samples were removed from each test and blank vessel. The appropriate blank particle count was subtracted from that of the test culture to obtain the cell density.

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 culture medium control.

The exposure concentration was prepared by the addition of an appropriate quantity of test substance directly to 1 litre of culture medium in a volumetric flask. The flask was placed into a waterbath 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 contained 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. Using aseptic techniques, 100 ml volumes of the collected supernatant were dispensed to each test and blank vessel, with the remainder of the test solutions being used for physical and chemical analyses. The final solution was clear and colourless.

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

Analytical method

Samples were taken from the centre of the test solutions at 0 and 72 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]

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 using a factor of 60/28.

Physical and chemical parameters

The pH of both test solutions were measured at the start of the test with a calibrated pH meter using the excess remaining after filling the test vessels. At the end of the test the pH of two of the replicate test solutions (containing algae) from the culture medium control and the single test concentration were determined. The temperature of the incubator was measured daily by a thermometer calibrated to 0.1°C, and was continuously monitored, with hourly recording of values, using an electronic recording system. The light intensity was measured once during the study, using Skye Instruments photometers reading in lux and quantum units.

5.2 Results and discussion

Analytical data

The concentrations of silicon dioxide (test substance) was determined at the start and end of the test. 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 49% of the nominal value. A mean measured concentration equivalent to 0.54 mg/L of silicon dioxide was determined in the culture medium control. This is not considered to be test substance as measured levels of silicon were similar to background levels in fresh culture medium (0.20 mg/L silicon, equivalent to 0.42 mg/L silicon dioxide).

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

Biological data

The algal cell densities measured at each time period are given in Table A7_4_1_3-5. The means of these values are also shown in Table A7_4_1_3-5 and are plotted as growth curves in Figure 1.

The OECD Guideline specifies that the cell concentration in the control cultures should have increased by a factor of at least 16 within 3 days. The mean cell densities in the culture medium control and test concentration were observed to increase by factors of 13 and 420 respectively within three days.

The poor growth observed in the culture medium control is difficult to explain. Microscopic evaluation at the end of the test showed that the low levels of bacteria present would not be expected to inhibit alga growth. Limited additional investigation, commencing at the same time, showed that the addition of fresh sodium bicarbonate solution to 3 day old control replicates did not stimulate growth, but that aliquots of control alga grew vigorously, when transferred to freshly prepared medium.

It can only be concluded that the medium was degraded in some way during test pre-treatment (5 days stirring at 30°C), an effect mitigated by the presence of the test substance.

The EC_{50} is defined as the concentration of test substance which results in a 50 per cent reduction in either growth or growth rate relative to the control.

The NOEC (no observed effect concentration) in this guideline is the highest concentration tested at which the measured parameter shows no

significant inhibition of growth relative to control values.

Since the test exposure concentration growth far exceeded that of the control (even with exclusion of the apparently enhanced E replicate, mean cell densities were still greater by a factor of nearly 12×), statistical analyses were not considered appropriate.

Areas under the growth curve

The area under the growth curve, 0 to 72 hours (0 to 3 days) was calculated for each replicate culture, according to the formula given in the OECD Guideline.

$$\text{Area} = \frac{(N_0 + N_1) - 2N_0}{2} \times t_1 + \frac{(N_1 + N_2) - 2N_0}{2} \times (t_2 - t_1) + \frac{(N_{n-1} + N_n) - 2N_0}{2} \times (t_n - t_{n-1})$$

whereN_0=Cell density at start of test

N_1=Cell density at t_1

N_n=Cell density at t_n

t_1=Time (days) of first measurement after start of test

t_2=Time (days) of second measurement after start of test

t_n=Time (days) of n^{th} measurement after start of test

The mean areas under the growth curve are given in Table 3, together with the area expressed as a percentage of the culture medium control. As no inhibition was observed the E_bC_{50} is considered to be greater than the exposure concentration.

Therefore, based on the mean measured test concentration:

No observed effect concentration (NOEC)= 54 mg/L

Lowest observed effect concentration (LOEC)> 54 mg/L

Median effective concentration, biomass (E_bC50) > 54 mg/L

Growth rates

The growth rate, 0 to 72 hours (0 to 3 days) was calculated for each replicate culture, according to the formula.

$$\text{Growth rate} = \frac{\text{Log}_n(N_2 / N_1)}{t}$$

where N_1=Cell density at start of test

N_2=Cell density at end of test

t=Time interval (days)

As no inhibition was observed the E_rC_{50} is considered to be greater than the exposure concentration.

Therefore, based on the mean measured test concentration:

No observed effect concentration (NOEC)= 54 mg/L

Lowest observed effect concentration (LOEC)> 54 mg/L

Median effective concentration, growth rate (E_rC_{50})> 54 mg/L

Physical and chemical data

At the start of the test the pH was 7.5 and at the end of the test ranged from 7.8 to 8.7 (Table A7_4_1_3-3). A maximum increase of 1.2 pH units was observed over the test duration. This pH shift was considered

		to be a function of the high growth factors observed (mean exposure concentration 72 hour cell density = 420 × the 0 hour initial inoculum density). The pH shift occurred despite a high orbital shaking rate of 160 rpm to improve mass transfer of carbon dioxide into the test solutions. The daily temperature measurements recorded, by thermometer, in the incubator ranged from 24.4 to 24.5°C. The hourly temperature measurements, recorded automatically, remained within 24 ± 2°C. The light intensity, measured once during the study, was 7890 lux (by cosine receptor). This was also measured in terms of quantum response and was 99 μ Einsteins m^{-2} s^{-1}.
5.2.1	NOE_rC	54 mg/L
5.2.2	E_{r50}	> 54 mg/L
5.2.3	E_bC_{50}	> 54 mg/L
5.3	**Conclusion**	See also Table 3.1. The concentration of the test substance at the end of the test was >80% of the initial concentration. However, cell concentration in control cultures were not increased by a factor of 16 or more. As discussed above in 5.2, the poor growth observed in the culture medium control is difficult to explain although it may be due to pre-treatment of the algal medium to produce acceptable solubility of the test substance. Notwithstanding this, cell concentration increased in the test vessels, demonstrating lack of toxicity of the test substance therefore repeating the test would only serve to prove that control cultures will grow without test substance and will prove nothing further about the test substance itself.
5.3.1	Reliability	1
5.3.2	Deficiencies	Yes. Cell concentration in controls did not increase by a factor of 16 or more. Notwithstanding this, cell concentration increased in the test vessels, demonstrating lack of toxicity of the test substance therefore repeating the test would only serve to prove that control cultures will grow without test substance and will prove nothing further about the test substance itself.

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3

	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_3-1:Test organisms

Criteria	Details
Species	*Selenatrum capricornutum*
Strain	ATCC 22662
Source	Brixham Environmental Laboratory, Brixham, Devon, UK
Laboratory culture	Yes
Method of cultivation	Maintained under axenic conditions.
Pretreatment	The culture was grown in the medium, and under the environmental conditions, described for the test.
Initial cell concentration	1.01 x 10^4 cells/mL

Table A7_4_1_3-2:Test system

Criteria	Details
Volume of culture flasks	250 mL
Culturing apparatus	Gallenkamp type INR-401 orbital incubator
Light quality	Continuous "cool-white" illumination
Procedure for suspending algae	Orbital shaking at 160 rpm
Number of vessels/ concentration	Six replicate cultures of the culture medium control and single concentration of test substance were employed. The positions of the test vessels in the incubator were randomised by rows, and re-randomised daily. One blank vessel (without algal inoculum) for the culture medium control and each test concentration was incubated concurrently.
Test performed in closed vessels due to significant volatility of TS	No. However, vessels were closed with polyurethane foam bungs.

Table A7_4_1_3-3:Test conditions

Criteria	Details				
Test temperature	24.4 to 24.5°C				
pH	Nominal loading rate of test substance (mg/L)	Mean measured conc. of test substance (mg/L)	pH		
			0 hours	72 hours	
				Replicate A	Replicate B
	Culture control medium	-	7.5	7.8	7.8
	110	54	7.5	8.3	8.7
Aeration of dilution water	No				
Light intensity	The light intensity, measured once during the study, was 7890 lux (by cosine receptor). This was also measured in terms of quantum response and was 99 µ Einsteins m^{-2} s^{-1}.				
Photoperiod	24 hours				

Table A7_4_1_3-4: Analytical results [a]

Nominal loading rate of Gasil 23D ($mg\ l^{-1}$)	0 hours		72 hours		Mean conc of silicon dioxide over the test duration (mg/L)	Mean measured conc as % of nominal
	Measured conc. of silicon (mg/L)	Silicon dioxide equivalent (mg/L)	Measured conc. of silicon (mg/L)	Silicon dioxide equivalent (mg/L)		
Dilution water control	0.23[c]	0.49	0.27[c]	0.58	- [b]	-
110	25[d]	54	25[e]	54	54 [c]	49

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 culture medium (0.20 mg/L silicon, equivalent to 0.42 mg/L silicon dioxide)

c Calculated using the arithmetic mean of the 0 and 72 hour silicon dioxide results

d Mean of triplicate analyses: 25, 25, 25 mg/L

e Mean of triplicate analyses: 25, 25, 25 mg/L

Table A7_4_1_3-5: Cell concentration data

Test-Substance Concentration (effective) [mg/L]	Replicate	Cell concentrations (mean values) [x 10^4 cells/mL]							
		measured				Percent of control			
		0 h	24 h	48 h	72 h	0 h	24 h	48 h	72 h
Culture control medium	A	1.01	3.66	6.07	9.71	Not reported	Not reported	Not reported	Not reported
Culture control medium	B	1.01	3.33	7.62	17.3	Not reported	Not reported	Not reported	Not reported
Culture control medium	C	1.01	3.01	5.68	8.68	Not reported	Not reported	Not reported	Not reported
Culture control medium	D	1.01	2.75	5.89	8.08	Not reported	Not reported	Not reported	Not reported
Culture control medium	E	1.01	2.99	7.63	17.7	Not reported	Not reported	Not reported	Not reported
Culture control medium	F	1.01	3.89	8.35	20.3	Not reported	Not reported	Not reported	Not reported
Culture control medium	Mean	1.01	3.27	6.87	13.6	Not reported	Not reported	Not reported	Not reported
54 (m)	A	1.01	4.68	19.7	1233	Not reported	Not reported	Not reported	Not reported
54 (m)	B	1.01	4.82	24.5	158	Not reported	Not reported	Not reported	Not reported
54 (m)	C	1.01	4.67	18.9	125	Not reported	Not reported	Not reported	Not reported
54 (m)	D	1.01	4.39	19.6	131	Not reported	Not reported	Not reported	Not reported
54 (m)	E	1.01	6.58	58.5	1780	Not reported	Not reported	Not reported	Not reported
54 (m)	F	1.01	5.06	41.1	227	Not reported	Not reported	Not reported	Not reported
54 (m)	Mean	1.01	5.03	30.4	424	Not reported	Not reported	Not reported	Not reported
Temperature [°C]		24±2°C	24±2°C	24±2°C	24±2°C				
pH		7.5	Not reported	Not reported	7.8[a], 7.8[b], 8.3[c], 8.7[d]				

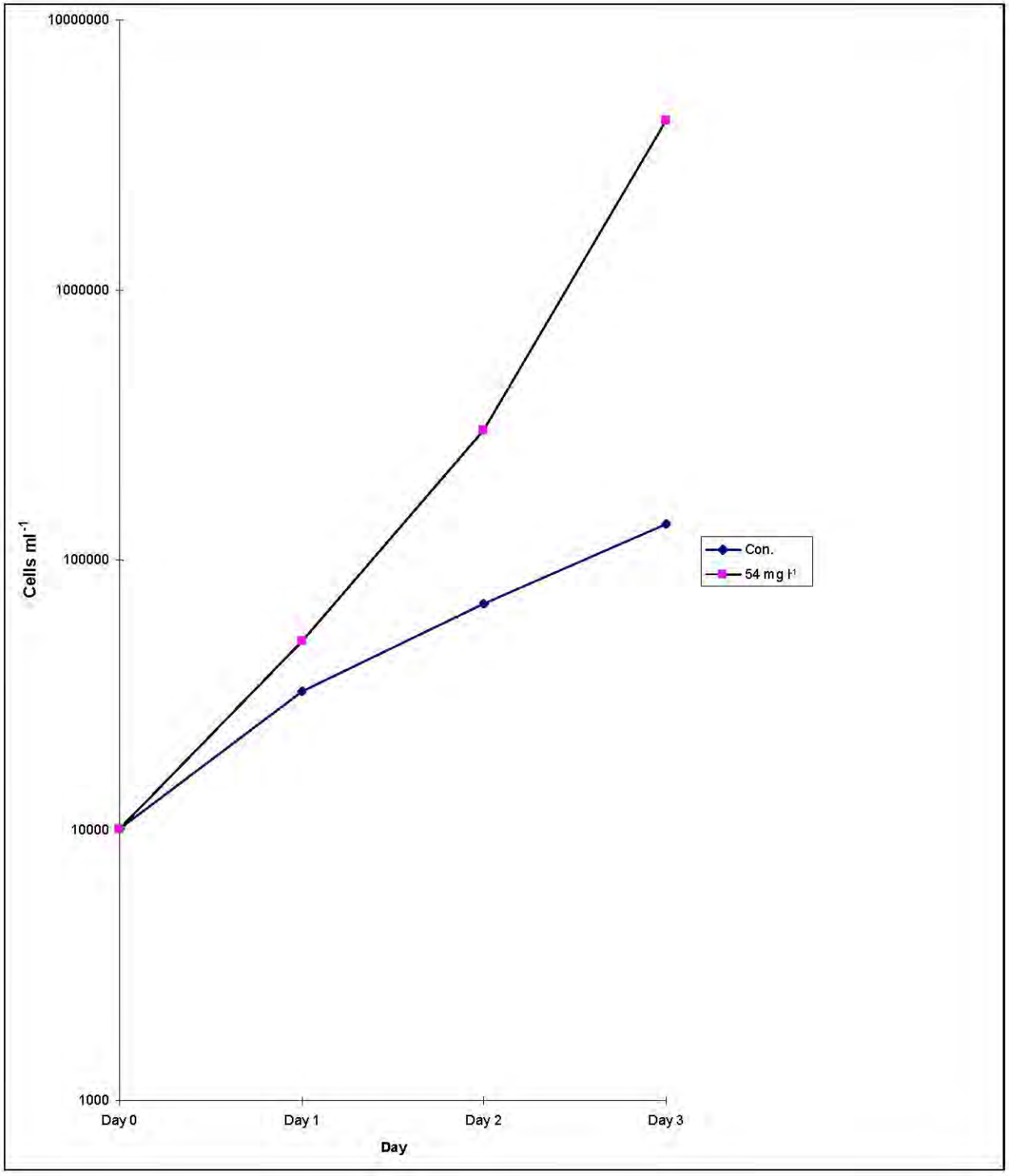
a Culture control medium Replicate A

b Culture control medium Replicate B

c Test substance Replicate A

d Test substance Replicate B

Fig 1 Effects on Growth of Green Alga *Selenastrum capricornutum* after 72 hours



3.Tables for Applicant's Summary and Conclusion

3.1Validity criteria for algal growth inhibition test according to OECD Guideline 201

	fulfilled	Not fullfilled
Cell concentration in control cultures increased at least by a factor of 16 within 3 days		4
Concentration of test substance ≥80% of initial concentration during test	4	

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

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 Test Guideline 209, Activated Sludge, Respiration Inhibition 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	Not applicable. Nominal concentration used.
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Not applicable.
3.3	**Reference substance**	Yes. 3,5-dichlorophenol (97%) as recommended in the OECD Guideline.
3.3.1	Method of analysis for reference substance	Not applicable.
3.4	**Testing procedure**	
3.4.1	Culture medium	A synthetic sewage mixture described by the OECD guideline was prepared containing the following constituents per litre of deionised

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

		water: 15.2 g of peptone, 10.5 g of meat extract, 2.9 g of urea, 0.7 g of NaCl, 0.4 g of $CaCl_2.2H_2O$, 0.2 g of $MgSO_4.7H_2O$ and 2.8 g of K_2HPO_4.
3.4.2	Inoculum / test organism	See table A7_4_1_4-1
3.4.3	Test system	See table A7_4_1_4-2
3.4.4	Test conditions	See table A7_4_1_4-3
3.4.5	Duration of the test	3 hours
3.4.6	Test parameter	Respiration inhibition.
3.4.7	Analytical parameter	Oxygen measurement.
3.4.8	Sampling	Measurement after 3 hours.
3.4.9	Monitoring of TS concentration	No
3.4.10	Controls	Control without test substance: 230 mL Activated sludge, 16 mL Synthetic sewage feed, 254 mL Water.
3.4.11	Statistics	A computer was used to calculate the respiration rate in each flask and compared it to the mean of the two control cultures. The dissolved oxygen concentration after the 3 hour aeration period was at least 6.0 mg O_2 l^{-1}. The respiration rate was measured over the linear part of the curve for approximately five minutes. The rates of oxygen uptake were expressed as mg O_2 l^{-1} h^{-1}. The respiration rates of the flasks dosed with the test or reference substance were expressed as percentages of the mean of the respiration rate of the control flasks, from which the percentage inhibition was derived: $$\%\,\text{inhibition} = \left[1 - \left[\frac{\text{Respiration rate of test flask}}{\text{Mean respiration rate of control flasks}}\right]\right]$$
		4 RESULTS
4.1	**Preliminary test**	Not performed
4.1.1	Concentration	Not applicable.
4.1.2	Effect data	Not applicable.
4.2	**Results test substance**	*Non-entry field*
4.2.1	Initial concentrations of test substance	1000 mg/L
4.2.2	Actual concentrations of test substance	Not applicable. Nominal concentration used.

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

4.2.3	Growth curves	See Table A7_4_1_4-4 for data.
4.2.4	Cell concentration data	Not applicable.
4.2.5	Concentration/ response curve	Not applicable. No inhibition occurred. See Table A7_4_1_4-4 for data.
4.2.6	Effect data	NOEC = 1000 mg/L
4.2.7	Other observed effects	None.
4.3	**Results of controls**	See Table A7_4_1_4-4.
4.4	**Test with reference substance**	Performed.
4.4.1	Concentrations	See Table A7_4_1_4-4.
4.4.2	Results	EC_{50} = 17 mg/L

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Study was performed in accordance with OECD Test Guideline 209, Activated Sludge, Respiration Inhibition Test. Adopted 4 April 1984.

Test substance

Test solutions were prepared by the direct addition of a known weight of test substance to a total volume of 500 ml deionised water, synthetic sewage and activated sludge as described in the experimental design Table A7_4_1_4-5.

Reference substance

A nominal 500 mg/L stock solution of the reference substance, 3,5-dichlorophenol, was prepared in deionised water. This stock solution was observed to be clear and colourless and its pH was measured as 6.4.

Activated sludge

Activated sludge was obtained from [redacted] one day prior to the exposure of test and reference substances. This works treats sewage of predominantly domestic origin.

On return to the laboratory, the activated sludge was settled and the concentrated sludge was washed with mineral medium comprising approximately 0.035 g of NaCl, 0.02 g of $CaCl_2.2H_2O$ and 0.01 g of $MgSO_4.7H_2O$ per litre of deionised water. The washed settled sludge was fed with 50 ml of OECD synthetic sewage feed per litre of sludge per day and aerated at room temperature, until it was used in the test.

The total filterable solids concentration was determined on the day of the test and was found to be 3543 mg/L. The pH was measured as 7.9, and was subsequently adjusted to 7.2 with 2 M hydrochloric acid prior to use.

Synthetic sewage

A synthetic sewage mixture described by the OECD guideline was prepared containing the following constituents per litre of deionised

water: 15.2 g of peptone, 10.5 g of meat extract, 2.9 g of urea, 0.7 g of NaCl, 0.4 g of $CaCl_2.2H_2O$, 0.2 g of $MgSO_4.7H_2O$ and 2.8 g of K_2HPO_4.

Experimental design

This test measures the respiration rate of an activated sludge 3 hours after feeding an excess, but standard amount, of a synthetic sewage and compares this with the respiration rate of the same activated sludge in the presence of the test chemical. 3,5-dichlorophenol is used as a reference substance as it has known inhibitory effects on respiration and ensures that the batch of sludge used in the test shows a normal level of sensitivity.

A single nominal 1000 mg/L concentration of test substance was prepared in duplicate together with three control culture flasks. Four flasks containing the reference substance, 3,5-dichlorophenol, at nominal concentrations of 3.2, 10, 32 and 100 mg/L were also prepared. In addition a single abiotic flask containing 100 mg/L 3,5-dichlrorphenol but no activated sludge was prepared. The experimental design is shown in Table A7_4_1_4-5.

Each flask contained an excess of the synthetic sewage, sufficient activated sludge to give final solids concentrations of 1600 mg/L, an appropriate quantity of either test substance or 3,5-dichlorophenol stock solution and aerated water to give a final flask contents volume of 500 ml. The exact quantities of each of these constituents are given in Table A7_4_1_4-5. The pH of each flask was measured before the start of the test.

Flasks were set up in batches of six and aerated at 20 ± 2°C for 3 hours. Each batch included a control flask and five test or reference substance flasks. The temperatures of the flask contents were measured at the end of the 3 hours aeration using a mercury-in-glass thermometer.

The respiration rate of each culture was measured after 3 hours and compared with the mean respiration rate of the two control cultures. The rate of oxygen uptake was measured in glass sample tubes into which microcathode oxygen electrodes were inserted. The electrodes were connected to an interface unit, which converted the current produced by the electrodes into dissolved oxygen readings. These were in turn transferred to a computer, which calculated the respiration rate in each flask and compared it to the mean of the two control cultures. The dissolved oxygen concentration after the 3 hour aeration period was at least 6.0 mg O_2 l^{-1}. The respiration rate was measured over the linear part of the curve for approximately five minutes. The rates of oxygen uptake were expressed as mg O_2 l^{-1} h^{-1}.

The respiration rates of the flasks dosed with the test or reference substance were expressed as percentages of the mean of the respiration rate of the control flasks, from which the percentage inhibition was derived:

$$\%\,\text{inhibition} = \left[1 - \left[\frac{\text{Respiration rate of test flask}}{\text{Mean respiration rate of control flasks}}\right]\right]$$

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

5.2	**Results and discussion**	The results are shown in Table A7_4_1_4-4. In test flasks dosed with Amorphous silicon dioxide, <10% inhibition was observed in the single tested concentration. The median effective concentration (EC50) is defined as the concentration, estimated from the data obtained, resulting in a 50% reduction in the respiration rate of activated sludge within the period of the test, therefore, 3 hour EC50 >1000 mg/L The 20% and 80% effect concentrations (EC20 and EC80) are defined as the concentrations, estimated from the data obtained, resulting in 20 and 80% reduction respectively in the respiration rate of activated sludge within the period of the test, therefore, 3 hour EC20 >1000 mg/L 3 hour EC80 >1000 mg/L The 10% effect concentration (EC10) is defined as the concentration, estimated from the data obtained, resulting in a 10% reduction in the respiration rate of activated sludge within the period of the test. Percentage inhibition less than or equal to 10% was within the expected experimental variability of the test and was considered not to be an effect of Amorphous silicon dioxide. The no observed effect concentration (NOEC) is therefore equivalent to the EC10 in this test, therefore, 3 hour NOEC = 1000 mg/L The reference substance, 3,5-dichlorophenol, caused substantial inhibition of the respiration rate of the activated sludge. From the results obtained the 3 hour EC50 value was estimated to be 17 mg/L (Fig 1). This is within the expected normal range of 5 to 30 mg/L indicating the sludge was responding normally and confirming the viability of the sludge organisms. The respiration rates in the two control flasks were within 15% of each other. Therefore, the mean control respiration rate was used in calculation of the percentage inhibition. The temperatures of the flask contents after the 3 hours aeration were all within the range 20 ± 2°C.
5.2.1	EC_{20}	3 hour EC20 >1000 mg/L
5.2.2	EC_{50}	3 hour EC50 >1000 mg/L
5.2.3	EC_{80}	3 hour EC80 >1000 mg/L
5.3	**Conclusion**	The reference material produced the expected inhibition as did controls. No inhibition occurred due to application of the test material. Dose of the test material is deemed to be acceptably high to validate this result.
5.3.1	Reliability	1
5.3.2	Deficiencies	No.

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

	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_4-1: Inoculum / Test organism

Criteria	Details
Nature	Activated sludge
Species	Not determined.
Strain	Not determined.
Source	[redacted] treating sewage of predominantly domestic origin.
Sampling site	Not determined.
Laboratory culture	No. See below.
Method of cultivation	Not applicable.
Preparation of inoculum for exposure	On return to the laboratory, the activated sludge was settled and the concentrated sludge was washed with mineral medium comprising approximately 0.035 g of NaCl, 0.02 g of $CaCl_2.2H_2O$ and 0.01 g of $MgSO_4.7H_2O$ per litre of deionised water. The washed settled sludge was fed with 50 ml of OECD synthetic sewage feed per litre of sludge per day and aerated at room temperature, until it was used in the test.
Pretreatment	The pH was measured as 7.9, and was subsequently adjusted to 7.2 with 2 M hydrochloric acid prior to use.
Initial cell concentration	The total filterable solids concentration was determined on the day of the test and was found to be 3543 mg l^{-1}.

Table A7_4_1_4-2: Test system

Criteria	Details
Culturing apparatus	Standard control culture flasks.
Number of culture flasks/concentration	6
Aeration device	Not specified in report.
Measuring equipment	Microcathode oxygen electrodes
Test performed in closed vessels due to significant volatility of TS	No.

Table A7_4_1_4-3: Test conditions

Criteria	Details		
Test temperature	The temperatures of the flask contents were measured at the end of the 3 hours aeration using a mercury-in-glass thermometer. The temperatures of the flask contents after the 3 hours aeration were all within the range 20 ± 2°C.		
pH	Ph		
		Start	End
	Control	7.3	8.1
	3,5-DCP [a]	7.1	6.9
	3,5-DCP	7.2	8.1
	3,5-DCP	7.3	8.1
	3,5-DCP	7.2	8.0
	3,5-DCP	7.3	8.1
	Control	7.3	8.1
	Control	7.3	8.1
	Amorphous silicon dioxide	7.3	8.0
	Amorphous silicon dioxide	7.2	8.0
Aeration of dilution water	Yes. Method not specified in report.		
Suspended solids concentration	1600 mg/L		

[a] 3,5-dichlorophenol

Table A7_4_1_4-4: Inhibition Results

Test substance	Nominal test concentration ($mg\ l^{-1}$)	pH		Respiration rate ($mg\ O_2\ l^{-1}\ h^{-1}$)	Percentage mean control respiration rate[a]	Percentage inhibition
		Start	End			
Control	-	7.3	8.1	45.2	-	-
3,5-DCP[b]	100 (abiotic)	7.1	6.9	-0.8		
3,5-DCP	100	7.2	8.1	3.1	7	93
3,5-DCP	32	7.3	8.1	15.4	35	65
3,5-DCP	10	7.2	8.0	27.4	62	38
3,5-DCP	3.2	7.3	8.1	38.5	87	13
Control	-	7.3	8.1	43.4	-	-
Control[c]	-	7.3	8.1	41.0	-	-
Amorphous silicon dioxide	1000	7.3	8.0	43.0	97	<10
Amorphous silicon dioxide	1000	7.2	8.0	41.9	95	<10

[a] Mean control respiration rate = 44.3 $mg\ O_2\ l^{-1}\ h^{-1}$

[b] 3,5-dichlorophenol

[c] Not used in calculation of mean respiration rate

Table A7_4_1_4-5: Experimental design

Test substance	Nominal test concentration (mg/L)	Volume of activated sludge (mL)	Volume of synthetic sewage feed (mL)	Nominal mass of test substance (mg)	Volume of stock[a] (mL)	Volume of water[b] (mL)
Control	-	230	16	-	-	254
3,5-DCP[c]	100 (abiotic)	-	16	-	100	384
3,5-DCP	100	230	16	-	100	154
3,5-DCP	32	230	16	-	32	222
3,5-DCP	10	230	16	-	10	244
3,5-DCP	3.2	230	16	-	3.2	251
Control	-	230	16	-	-	254
Control[d]	-	230	16	-	-	254
Gasil 23D	1000	230	16	500	-	254
Gasil 23D	1000	230	16	500	-	254

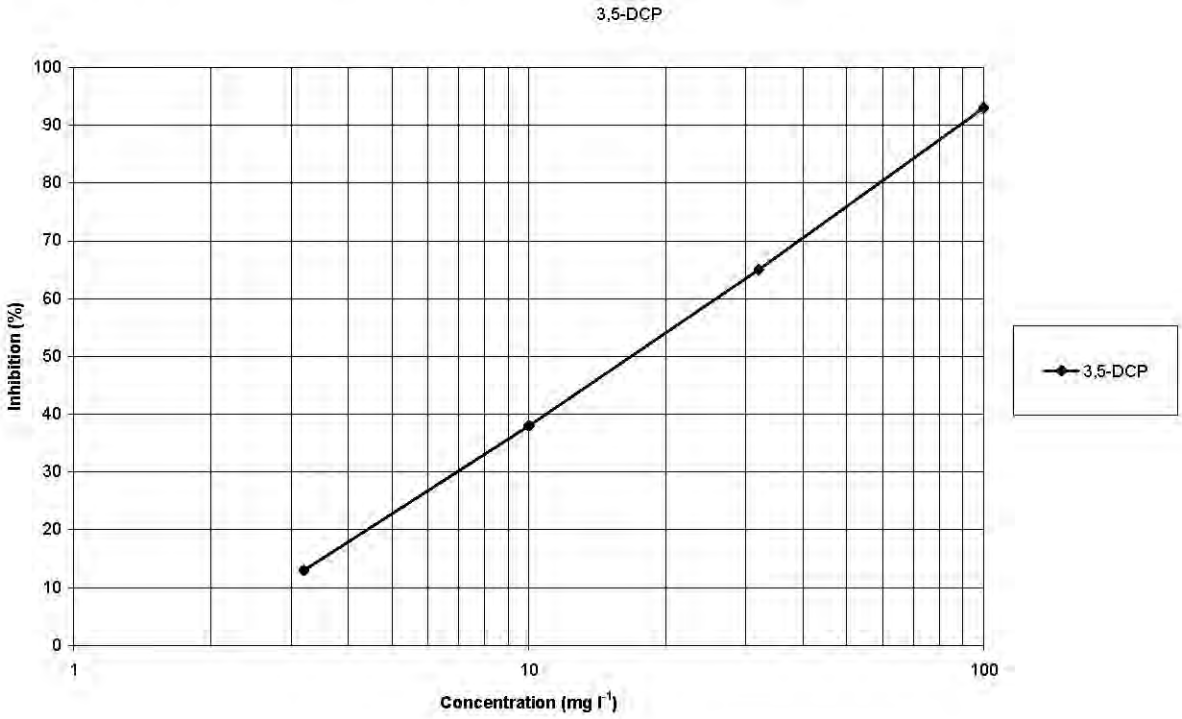
a The stock solution concentration of 3,5-dichlorophenol was 500 mg/L test substance added by direct weigh procedure

b To give a final volume of 500 ml in each flask

c 3,5-dichlorophenol

d Additional control flask. Data not used in the calculation of results

Fig. 1 Effect of 3,5-dichlorophenol on the respiration of activated sludge



Section 7.4.2 Annex Point/TNsG Annex IIA, VII.7.5	**Bioconcentration** 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:	"Bioconcentration" is the process leading to a higher concentration of, for example, a pesticide in an organism than in environmental media to which it is exposed. The "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" states that the following are indicators of bioaccumulation potential: ▪ if the substance has a partition coefficient log Kow ≥ 3 or ▪ the substance is highly adsorptive or ▪ the substance belongs to a class of substances known to have a potential to accumulate in living organisms or ▪ there are indications from structural features From the data available, silicon dioxide is not expected to have an intrinsic potential for bioconcentration in aquatic organisms, on the basis that it has an estimated partition coefficient of 0.53 (refer to Document IIIA, section 3.9 for detail).	
Undertaking of intended data submission [ ]	Not applicable	

Section 7.4.2 Annex Point/TNsG Annex IIA, VII.7.5	**Bioconcentration** 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 7.4.3 Annex Point/TNsG Annex IIIA, XIII.2	**Effects on Aquatic Organisms, 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 on the effects on aquatic organisms are required only if the results of data submitted for the end points 7.4.1.1, 7.4.1.2, 7.4.1.3 and 7.4.1.4 indicate a danger to the environment. As the results of the tests submitted for the end points 7.4.1.1, 7.4.1.2, 7.4.1.3 and 7.4.1.4 do not indicate that silicon dioxide poses a danger to the environment, no additional studies to determine the effect of silicon dioxide to aquatic organisms have been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3 Annex Point/TNsG Annex IIIA, XIII.2	**Effects on Aquatic Organisms, 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 7.4.3.1 Annex Point/TNsG Annex IIIA, XIII.2.1	**Prolonged toxicity to an appropriate species of fish.** 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 on the effects on aquatic organisms are required only if the results of data submitted for the end points 7.4.1.1, 7.4.1.2, 7.4.1.3 and 7.4.1.4 indicate a danger to the environment. As the results of the tests submitted for the end points 7.4.1.1, 7.4.1.2, 7.4.1.3 and 7.4.1.4 do not indicate that silicon dioxide poses a danger to the environment, it is not considered necessary to submit data that considers prolonged toxicity of silicon dioxide to fish.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.1 **Annex Point/TNsG** **Annex IIIA, XIII.2.1**	**Prolonged toxicity to an appropriate species of fish.** 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 7.4.3.2 **Annex Point/TNsG** **Annex IIIA, XIII.2.2**	**Effects on reproduction and growth rate of fish.** 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 on the effects on aquatic organisms are required only if the results of data submitted for the end points 7.4.1.1, 7.4.1.2, 7.4.1.3 and 7.4.1.4 indicate a danger to the environment. As the results of the tests submitted for the end points 7.4.1.1, 7.4.1.2, 7.4.1.3 and 7.4.1.4 do not indicate that silicon dioxide poses a danger to the environment, it is not considered necessary to submit data that considers the effect of silicon dioxide on the reproduction and growth rate of fish.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.2 Annex Point/TNsG Annex IIIA, XIII.2.2	**Effects on reproduction and growth rate of fish.** 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 7.4.3.3.1 Annex Point/TNsG Annex IIIA, XIII.2.3	**Bio-accumulation in an appropriate species of fish.** 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 this information is only required when there is a risk of secondary poisoning or there are other features indicating bio-accumulation. The environmental risk assessment for silicon dioxide shows that there is no risk of secondary poisoning under normal conditions of use in Rentokil Initial's insecticide (PT18) products. As shown in Document IIIA, section 7.4.2, silicon dioxide is not expected to have an intrinsic potential for bioconcentration. It is for these reasons that it is not considered necessary to submit additional data about bioaccumulation in an appropriate species of fish.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.3.1 **Annex Point/TNsG** **Annex IIIA, XIII.2.3**	**Bio-accumulation in an appropriate species of fish.** 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 7.4.3.3.2 Annex Point/TNsG Annex IIIA, XIII.2.4	**Bio-accumulation in an appropriate invertebrate species.** 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 this information is required for certain product types, especially if direct release to marine/brackish water occurs. Under normal conditions of use in Rentokil Initial's insecticide (PT18) products, silicon dioxide is not intended to be either used or released into marine/brackish water. In addition, the environmental risk assessment for silicon dioxide shows that there is no risk of secondary poisoning under normal conditions of use in Rentokil Initial's insecticide (PT18) products. As shown in Document IIIA, section 7.4.2, silicon dioxide is not expected to have an intrinsic potential for bioconcentration. It is for these reasons that it is not considered necessary to submit additional data about bioaccumulation in an appropriate invertebrate species.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.3.2 Annex Point/TNsG Annex IIIA, XIII.2.4	**Bio-accumulation in an appropriate invertebrate species.** 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 7.4.3.4 **Annex Point/TNsG** **Annex IIIA, XIII.2.4**	**Effects on reproduction and growth rate with an appropriate invertebrate species.** 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 this information is only required when chronic exposure is expected or there are other features indicating the need for this test. The core base data set for silicon dioxide does not indicate that silicon dioxide poses a danger to the environment. In addition, the environmental risk assessment for silicon dioxide shows that no chronic exposure to fish is expected under normal conditions of use in Rentokil Initial's insecticide (PT18) products. It is for these reasons that a study to determine the effects of silicon dioxide on the reproduction and growth rate of an appropriate invertebrate species has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.4 **Annex Point/TNsG** **Annex IIIA, XIII.2.4**	**Effects on reproduction and growth rate with an appropriate invertebrate species.** 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 7.4.3.5 Annex Point/TNsG Annex IIIA, XIII.3.4	**Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk.** 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 this information is only required if the data from other ecotoxicity tests indicates the need to do so, or if there is a need indicated by the intended use. Other ecotoxicity tests, and the environmental risk assessment and use pattern for silicon dioxide do not indicate that further testing is required. It is on this basis that data on the effects of silicon dioxide on specific non-target organisms (flora and fauna) has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.5 Annex Point/TNsG Annex IIIA, XIII.3.4	**Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk.** 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 7.4.3.5.1 Annex Point/TNsG Annex IIIA, XIII.3.4	Effects on sediment dwelling organisms 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 this information is only required if the active substance partitions to, and persists in, aquatic sediments such that sediment dwelling organisms are likely to be exposed to the active substance. The core base data set for silicon dioxide does not indicate that silicon dioxide poses a danger to sediment dwelling organisms. In addition, the environmental risk assessment for silicon dioxide shows that no exposure of sediment dwelling organisms is expected under normal conditions of use in Rentokil Initial's insecticide (PT18) products. It is for these reasons that a study to determine the effects of silicon dioxide on sediment dwelling organisms has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.5.1 Annex Point/TNsG Annex IIIA, XIII.3.4	**Effects on sediment dwelling organisms** 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 7.4.3.5.2 **Annex Point/TNsG** **Annex IIIA, XIII.3.4**	**Aquatic plant toxicity** 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 further studies on the effects on aquatic organisms, such as aquatic plants, are required only if the results of data submitted for the end points 7.4.1.1, 7.4.1.2, 7.4.1.3 and 7.4.1.4 indicate a danger to the environment. As the results of the tests submitted for the end points 7.4.1.1, 7.4.1.2, 7.4.1.3 and 7.4.1.4 do not indicate that silicon dioxide poses a danger to the environment, it is not considered necessary to submit data that considers toxicity of silicon dioxide to aquatic plants.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.5.2 Annex Point/TNsG Annex IIIA, XIII.3.4	**Aquatic plant toxicity** 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 7.5.1.1 Annex Point/TNsG Annex IIA, VII.7.4	**Inhibition to microbial activity (terrestrial)** 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 this test is required only if the risk assessment for the terrestrial compartment indicates a concern. The environmental risk assessment for silicon dioxide does not indicate that it poses a risk to the terrestrial compartment. It is on this basis that it is not considered necessary to submit data on the effect of silicon dioxide on the inhibition of microbial activity in the terrestrial compartment.	
Undertaking of intended data submission [ ]	Not applicable	

Section 7.5.1.1 Annex Point/TNsG Annex IIA, VII.7.4	**Inhibition to microbiological activity (terrestrial)** 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 A7.5.1.2 Annex Point / TNsG Annex IIIA XIII 3.2	**Earthworm, acute toxicity test** 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:	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 required only if the risk assessment for the terrestrial compartment indicates a concern. The information on the environmental exposure scenario for silicon dioxide (as given in Document IIIB, Section 7.1) does not indicate that it poses a risk to the terrestrial compartment. It is on this basis that it is not considered necessary to submit data on the acute toxicity of silicon dioxide to earthworms.	
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 A7.5.1.3 Annex Point / TNsG Annex IIIA XIII 3.4	Acute Toxicity to Plants 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 this test is required only if the risk assessment for the terrestrial compartment indicates a concern. The environmental risk assessment for silicon dioxide does not indicate that it poses a risk to the terrestrial compartment. It is on this basis that it is not considered necessary to submit data on the acute toxicity of silicon dioxide to plants.	
Undertaking of intended data submission [ ]	Not applicable.	

Section A7.5.1.3 Annex Point / TNsG Annex IIIA XIII 3.4	**Acute Toxicity to Plants** 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 A7.5.2.1 Annex Point / TNsG Annex IIIA XIII 3.2	**Reproduction Study with Earthworms or Other Soil Non-target Macro-organisms** 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 this test is required only if the risk assessment for the terrestrial compartment indicates a concern. The environmental risk assessment for silicon dioxide does not indicate that it poses a risk to the terrestrial compartment. It is on this basis that it is not considered necessary to submit data to determine the effects of silicon dioxide on the reproduction of earthworms or other soil non-target macro-organism.	
Undertaking of intended data submission [ ]	Not applicable.	

Section A7.5.2.1 Annex Point / TNsG Annex IIIA XIII 3.2	**Reproduction Study with Earthworms or Other Soil Non-target Macro-organisms** 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 A7.5.2.2 Annex Point / TNsG Annex IIIA XIII 3.4	**Long-term Test with Terrestrial Plants** 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 this test is required only if the risk assessment for the terrestrial compartment indicates a concern, or there is likely to be long-term exposure to the active substance. The environmental risk assessment for silicon dioxide does not indicate that it poses a risk to the terrestrial compartment, or is there long term exposure. It is on this basis that it is not considered necessary to submit data to determine the effects of long-term exposure of silicon dioxide to terrestrial plants.	
Undertaking of intended data submission [ ]	Not applicable.	

Section A7.5.2.2 Annex Point / TNsG Annex IIIA XIII 3.4	**Long-term Test with Terrestrial Plants** 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 A7.5.3.1.1. Annex Point / TNsG Annex IIIA XIII 1.1	**Acute Oral Toxicity – Birds** 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 this test is required for certain product types if direct exposure to birds is possible. It is not considered necessary to submit data to determine the acute oral toxicity of silicon dioxide to birds for the following reasons: ▪ Silicon dioxide, under normal conditions of use in Rentokil Initial's insecticide (PT 18) products will be applied indoors only. ▪ Data submitted in Document IIIA, section 7.4.2 shows that silicon dioxide is not expected to have an intrinsic potential for bioaccumulation. ▪ The environmental risk assessment for silicon dioxide shows there is no risk of secondary poisoning under normal conditions of use in Rentokil Initial's insecticide (PT 18) products. ▪ There is no data available to suggest that silicon dioxide is hazardous to birds. It is for these reasons that a study determining the acute oral toxicity of silicon dioxide to birds has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable.	

Section A7.5.3.1.1. Annex Point / TNsG Annex IIIA XIII 1.1	**Acute Oral Toxicity – Birds** 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 A7.5.3.1.2. Annex Point / TNsG Annex IIIA XIII 1.2	**Short Term Toxicity –Birds** Section 7: Ecotoxiological 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 this test is required for certain product types if direct exposure to birds is possible. It is not considered necessary to submit data to determine the short term toxicity of silicon dioxide to birds for the following reasons: ▪ Silicon dioxide, under normal conditions of use in Rentokil Initial's insecticide (PT 18) products will be applied indoors only. ▪ Data submitted in Document IIIA, section 7.4.2 shows that silicon dioxide is not expected to have an intrinsic potential for bioaccumulation. ▪ The environmental risk assessment for silicon dioxide shows there is no risk of secondary poisoning under normal conditions of use in Rentokil Initial's insecticide (PT 18) products. ▪ There is no data available to suggest that silicon dioxide is hazardous to birds. It is for these reasons that a study determining the short term toxicity of silicon dioxide to birds 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 A7.5.3.1.3. Annex Point / TNsG Annex IIIA XIII 1.3	**Effects on Reproduction – Birds** Section 7: Ecotoxiological 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 this test is required for certain product types if direct exposure to birds is possible. It is not considered necessary to submit data to determine the effects of silicon dioxide on the reproduction of birds, for the following reasons: ▪ Silicon dioxide, under normal conditions of use in Rentokil Initial's insecticide (PT 18) products will be applied indoors only. ▪ Data submitted in Document IIIA, section 7.4.2 shows that silicon dioxide is not expected to have an intrinsic potential for bioaccumulation. ▪ The environmental risk assessment for silicon dioxide shows there is no risk of secondary poisoning under normal conditions of use in Rentokil Initial's insecticide (PT 18) products. ▪ There is no data available to suggest that silicon dioxide is hazardous to birds. It is for these reasons that a study determining the effects of silicon dioxide on the reproduction of birds 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 A7.5.4.1 Annex Point / TNsG Annex IIIA XIII 3.1	**Acute Toxicity to Honeybees and other Beneficial Arthropods** Section 7: Ecotoxiological 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 this test is normally required for insecticides (PT 18), used outdoors. As silicon dioxide, under normal conditions of use in Rentokil Initial's insecticide (PT 18) products will be applied indoors only, it is not considered necessary to conduct this test.	
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 A7.5.5 Annex Point / TNsG Annex IIA, VII 7.5	**Bioconcentration, Terrestrial** Section 7: Ecotoxiological 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:	As shown in Document IIIA, section 7.4.2, silicon dioxide is not expected to have an intrinsic potential for bioconcentration in aquatic organisms. For the same reasons, silicon dioxide is not expected to have an intrinsic potential for bioconcentration in the terrestrial compartment. It is for these reasons that it is not considered necessary to submit additional data about bioaccumulation 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 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 A7.5.5.1 Annex Point / TNsG Annex IIA, VII 7.5	**Bioconcentration, Further Studies** Section 7: Ecotoxiological 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 test on bioconcentration in earthworms is required if the risk assessment for secondary poisoning would suggest a concern for predators. The environmental risk assessment for silicon dioxide shows there is no risk of secondary poisoning under normal conditions of use in Rentokil Initial's insecticide (PT 18) products. As there is no concern for predators, the test to determine bioconcentration of silicon dioxide in earthworms is not considered necessary.	
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 A7.5.6 Annex Point / TNsG Annex IIIA XIII 3.4	**Effects on Other Terrestrial Non-Target Organisms** 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 this information is only required if a concern for the terrestrial compartment is indicted by the risk assessment or if there is likely to be long term exposure to the active substance. The environmental risk assessment for silicon dioxide does not indicate that it poses a risk to the terrestrial compartment, or is there long-term exposure. It is on this basis that it is not considered necessary to submit data to determine the effects of silicon dioxide on other terrestrial non-target organisms.	
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 A7.5.7.1 Annex Point / TNsG Annex IIIA XIII 3.4	**Effects on Mammals** 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 this information is only required if a concern for the direct/indirect exposure for mammals is possible, and there is a severe risk for the terrestrial environment. The environmental risk assessment for silicon dioxide does not indicate that it poses a risk to the terrestrial environment. The toxicity profile of silicon dioxide as shown in Document IIIA, Section 6 Toxicological and Metabolic Studies does not indicate a concern regarding toxicity to mammals. It is for these reasons that it is not considered necessary to determine the effect of increased silicon dioxide exposure to mammals. Given the above justification, it is not necessary to submit data to meet the following data end points: 7.5.7.1.1 Acute oral toxicity (mammals) 7.5.7.1.2 Short term toxicity (mammals) 7.5.7.1.3 Effects on reproduction (mammals) Note that these points have been addressed for silicon dioxide in Document IIIA, Section 6 Toxicological and Metabolic Studies. Further studies are not required.	
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 A7.6 Summary of ecotoxicological effects and fate and behaviour in the environment.

Note that the following information is identical to that found in Document IIA.

4 ENVIRONMENTAL EFFECTS ASSESSMENT

4.1 FATE AND DISTRIBUTION IN THE ENVIRONMENT

4.1.1 Degradation

4.1.1.1 Biodegradation (1 of 2)

Guideline / Test method	Test type	Test parameter	Inoculum Type	Inoculum Conc	Inoculum Adaptation	Additional substrate	Test substance conc.	Degradation Incubation period	Degradation Degree [%]	Remarks	Reference
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Ready Biodegradability: Silicon dioxide is an inorganic chemical but the approved EC method C4 (a –f) applies only to organic compounds and the "TNsG" state that the ready biodegradation test is required only of organic compounds. Therefore a ready biodegradation test for silicon dioxide has not been submitted.	Document IIIA, Section 7.1.1.2.1
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Inherent Biodegradability: Silicon dioxide is an inorganic chemical but the approved EC methods C9 and C12 apply only to water-soluble, non-volatile organic substances. Therefore an inherent biodegradation test for silicon dioxide has not been submitted.	Document IIIA, Section 7.1.1.2.2
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Biodegradation in sea water: Silicon dioxide is an inorganic chemical but the process applies only to organic compounds. Silicon dioxide is not intended to be either used or released into marine environments. Therefore a biodegradation test for silicon dioxide in seawater has not been submitted.	Document IIIA, Section 7.1.1.2.3
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Biological sewage treatment – aerobic biodegradation: Silicon dioxide is an inorganic chemical but the process applies only to organic compounds. Therefore a test to determine the aerobic biodegradation of silicon dioxide in sewage has not been submitted.	Document IIIA, Section 7. 1.2.1.1
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Biological sewage treatment – anaerobic biodegradation: Silicon dioxide is an inorganic chemical but the process applies only to organic compounds. Silicon dioxide is not intended to be exposed to anaerobic conditions, such as manure storage facilities in animal housing. Therefore a test to determine the anaerobic biodegradation of silicon dioxide in sewage has not been submitted.	Document IIIA, Section 7.1.2.1.2

4.1.1.1 Biodegradation (2 of 2)

Guideline / Test method	Test type	Test parameter	Inoculum			Additional substrate	Test substance conc.	Degradation		Remarks	Reference
			Type	Conc	Adaptation			Incubation period	Degree [%]		
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Biodegradation in freshwater – aerobic aquatic degradation study: Silicon dioxide is an inorganic chemical but the approved EC methods for ready biodegradability (EC method C4 a-f) apply only to organic compounds and the "TNsG" state that the ready biodegradation test is required of organic compounds. Also the approved EC test methods C9 and C12 are designed to work with water-soluble, non-volatile organic substances. Therefore an aerobic aquatic biodegradation study for silicon dioxide has not been submitted.	Document IIIA, Section 7.1.2.2.1
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Biodegradation in freshwater – water/sediment degradation study Under normal conditions of use silicon dioxide will not be applied directly or indirectly to the sediment in aquatic systems. In addition: silicon dioxide is an inorganic chemical and the approved EC methods for ready biodegradability (EC method C4 a-f) apply only to organic compounds. Also the "TNsG" state that the ready biodegradation test is required of organic compounds. Inherent biodegradability (A7.1.1.2.2) is technically not feasible as the approved EC test methods C9 and C12 are designed to work with water-soluble, non-volatile organic substances. Therefore a study to determine the biodegradation of silicon dioxide in freshwater/sediment has not been submitted.	Document IIIA, Section 7.1.2.2.2

Footnotes

1. It is not considered necessary to determine rate and route of degradation in aquatic systems including the identification of metabolites (Document IIIA, 7.1.2) for the following reasons:

a) Testing for the ready biodegradability (Document IIIA, Section 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.

b) Inherent biodegradability (Document IIIA, Section 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.

4.1.1.2 Abiotic Degradation

Hydrolysis

Guideline /Test Method	pH	Temperature [°C]	Initial TS concentration C_0 [mol/l]	Reaction rate Constant, K_h [1/s x 10^5]	Half-life, DT_{50} [h]	Coefficient of correlation, r_2	Remarks	Reference
N/A	N/A	N/A	N/A	N/A	N/A	N/A	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.	Document IIIA, Section 7.1.1.1.1

Photolysis in water

Guideline/ Test Method	Initial Molar TS concentration	Total Recovery of Test Substance [% of appl. a.s.]	Photolysis rate constant (k^c_p)	Direct photolysis sunlight rate constant (K_{pE})	Reaction quantum yield (0^c_E)	Half-life ($t_{1/2E}$)	Remarks	Reference
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	N/A	N/A	N/A	$K_{d(max)}$: The average maximum rate constants for the two replicates were 16 and 3 day^{-1} for summer and winter conditions at 50°N respectively.	N/A	N/A	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.	Document IIIA, Section 7.1.1.1.2