	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	

Table 4-2: Standard form for justification of the non-submission of data

Section 6.17 **Annex Point IIIA, VI, 6**	**Toxic Effect of Metabolites from Treated Plants**	
	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 [4]	**Other justification** [ ]	
Detailed justification:	It is not necessary to submit tests to consider the toxic effect of metabolites from treated plants because the "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market : Guidance on Data Requirements for Active Substances and Biocidal Products" states that these tests are only required if the active ingredient is to be used to treat plants and these will be assessed under Directive 98/8/EC. It is not necessary to provide data on the toxic effect of metabolites from treated plants because carbon dioxide is not intended for use directly on plants or plant products.	
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	

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

3 HUMAN HEALTH EFFECTS ASSESSMENT

3.1 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

Result	Reference
Carbon dioxide is carried in the blood in three principle forms: • Dissolved in solution • As bicarbonate ions in red blood cells and blood plasma • Combined in the red blood cell, in the form of carboaminohaemoglobin. The body produces large volumes of carbon dioxide as a result of normal metabolic processes and is able to excrete it, while keeping the pH of the blood constant within a few hundredths of a pH unit and the tension of the blood is kept within a few millimetres of mercury without major dislocations of water or electrolytes. Under normal conditions of use, the use of carbon dioxide in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of carbon dioxide in air, outside normal atmospheric ranges. We can therefore expect it to be metabolised in the same way as the carbon dioxide naturally inhaled into the body as part of ventilation, and that produced by respiring cells. [1]	Document III-A6 Section 6.2

Footnotes

1. The process of production, transport and excretion of carbon dioxide in humans is well understood, as its toxicity profile. There are no metabolites of concern which are formed in mammals. It is on this basis that it is not scientifically necessary to submit additional data on metabolites of concern from carbon dioxide (the data requirements detailed in Document III-A 6.6.7).

3.2 ACUTE TOXICITY

Refer to page 8 for details of acute toxicity of carbon dioxide.

3.3 IRRITATION AND CORROSIVITY

Refer to page 9 for details of irritation and corrosivity potential of carbon dioxide.

3.4 SKIN SENSITISATION

Species	Method	Number of animals sensitised / total number of animals	Result	Remarks	Reference
Not applicable.	Not applicable.	Not applicable.	Not applicable.	It is not technically possible to determine the skin sensitisation potential of CO_2, using conventional assays because it is a gas. Notwithstanding this, it is also not considered necessary to determine the skin sensitisation potential of CO_2 because under normal conditions of use, CO_2 in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of CO_2 in air outside normal atmospheric ranges.	Document III-A6 Section 6.1.5

3.2 ACUTE TOXICITY

Route	Method Guideline	Method	Species Strain Sex No/group	Dose levels Duration of exposure	Value LD_{50}/LC_{50}	Remarks	Reference
Oral	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	It is not technically possible to determine the toxicity of carbon dioxide by the oral route, because carbon dioxide is a gas. Principle route of exposure will be by inhalation.	Document III-A6 Section 6.1.1
Dermal	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	It is not technically possible to determine the toxicity of carbon dioxide by the dermal route using conventional test methods, because carbon dioxide is a gas. Principle route of exposure will be by inhalation.	Document III-A6 Section 6.1.2
Inhalation	No set guideline followed. Refer to "Method" for summary of methodology followed.	Refer to notes under "Remarks".	Human	Refer to notes under "Remarks".	10% CO_2 * *See note under "remarks" for details about how this figure was derived.	Effects of excessive carbon dioxide exposure in man are well reported in the product literature. These studies have been summarised in Document IIIA Section 6.1.3, 6.4.3, 6.5 and 6.12. Generally, these studies were carried out for purposes other than just determining the LC_{50} or acute toxicity, but information on fatal and non fatal concentrations and major non-clinical effects can be used from them. Full details of the effects of carbon dioxide exposure in man, at concentrations up to 10% have been summarised in Document IIA, 3.10. As exposure to 10% carbon dioxide was not fatal to humans (although the effects experienced were very unpleasant), a value of 10% carbon dioxide has been used for the risk assessment for acute exposures to carbon dioxide. It should be noted that under normal conditions of use, the use of carbon dioxide in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of carbon dioxide in air, outside normal atmospheric ranges, and the studies available on man tend to address much longer periods of exposure than are likely to be relevant for the use of carbon dioxide in the representative product, Radar.	Document III-A6 Section A6.1.3

3.3 IRRITATION AND CORROSIVITY

Skin irritation

Species	Method	Average score 24, 48, 72h		Reversibility yes/no	Result	Remarks	Reference
Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	It is not technically possible to determine the skin irritation potential of CO_2 using conventional techniques because it is a gas. Notwithstanding this, it is also not considered necessary to determine the skin irritation potential of CO_2 because under normal conditions of use, the use of CO_2 in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of CO_2 in air outside normal atmospheric ranges.	Document III-A6 Section 6.1.4

Eye Irritation

Species	Method	Average score				Result	Reversibility Yes/no	Remarks	Reference
		Cornea		Iris	Redness Conjunctiva	Chemosis			
Not applicable.	Not applicable.	Not applicable.		Not applicable.	Not applicable.	Not applicable.	Not Applicable.	It is not technically possible to determine the eye irritation potential of CO_2 using conventional techniques because it is a gas. Notwithstanding this, it is also not considered necessary to determine the eye irritation potential of CO_2 because under normal conditions of use, the use of CO_2 in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of CO_2 in air outside normal atmospheric ranges.	Document III-A6 Section 6.1.4

3.5 REPEATED DOSE TOXICITY

Route	Duration of study	Species Strain Sex no/group	Dose levels Frequency of application	Results	LO(A)EL	NOAEL	Remarks	Reference
Inhalation	Refer to notes under "Remarks"	Refer to notes under "Remarks"	Refer to notes under "Remarks"	Refer to notes under "Remarks"	Refer to notes under "Remarks"	The long-term occupational exposure limit for carbon dioxide set in the UK is 5,000 ppm / 0.5% (8 hour time weighted average) while the short term occupational exposure limit is 15,000 ppm / 1.5% (15 minutes reference period)* *Refer to notes under "remarks" for details about why the occupational exposure limit for safe working conditions for carbon dioxide has been used.	Existing data on the subchronic toxicity of carbon dioxide are available, including data on man. However, it is acknowledged that this data, (which is summarised in Document IIIA Section 6.4.3) was carried out some time ago, and was therefore not carried out to current protocols or with current laboratory techniques. Given that this data is unavoidably weak, the current occupational exposure limit for safe working conditions with carbon dioxide has been used as the NOAEL value for the risk assessment. This is because: The use of carbon dioxide as a rodenticide does not increase carbon dioxide above levels found naturally in the atmosphere, and this is well below established maximum occupational exposure limits for safe working conditions. Occupational exposure work has been carried out in humans exposed to an environment with high $paCO_2$ values such as brewery workers. Such data have been used previously by a number of regulatory authorities to set national, international and supranational maximum exposure limits for safe working conditions, and all of these exposure limits are in general agreement. For the same reasons, a conventional 90-day subchronic oral toxicity test for carbon dioxide has not been conducted.	Document III-A6 Section 6.4.3

Footnotes

1. A 28-day repeated dose toxicity study (the data requirements detailed in Document III-A, 6.3.1, 6.3.2 and 6.3.3) is not required for carbon dioxide when an adequate 90 day study is available in a rodent.

2. A 90-day subchronic toxicity study by the oral and dermal route (the data requirements detailed in Document III-A 6.4.1 and 6.4.2) has not been submitted because it is not practicable to determine the oral or dermal toxicity of a gas using conventional techniques. In addition, the gaseous nature of carbon dioxide means that the most significant route of exposure is by inhalation, making this the most appropriate route for determining subchronic toxicity.

3.6 GENOTOXICITY

3.6.1 In vitro

Test system Method Guideline	Organism/ strain(s)	Concentrations tested	Result		Remark	Reference
			+S9	-S9		
			+/-/±	+/-/±		
Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	It is not technically possible to carry out an *in vitro* gene mutation study for CO_2 in bacteria or mammalian cells because it is present naturally in the environment and it is also naturally produced by all aerobic cells as a by-product of respiration. This makes it impossible to remove it from negative controls. Even if the test conditions were adjusted to account for this, the fact that test cells are continually producing CO_2 as a by-product of respiration means that there will be variable concentrations at a cellular level, making it impossible to interpret any observations made in the test. The same problems would also apply to an *in vitro* cytogenicity study in mammalian cells. Notwithstanding the above, it is also considered not necessary to determine the genotoxicity of CO_2 because under normal conditions of use, the use of CO_2 in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of CO_2 in air outside normal atmospheric ranges. [1]	Document III-A6 Section 6.6.1 Document III-A6 Section 6.6.2 Document III-A6 Section 6.6.3

Footnotes

1. It is not scientifically necessary, on the basis of the genotoxicity data available, to submit additional *in vivo* genotoxicity tests (the data requirements detailed in Document III-A 6.6.5)

3.6.2 In vivo

Type of test Method / Guideline	Species Strain Sex no/group	Frequency of application	Sampling times	Dose levels	Results	Remarks	Reference
Not applicable	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Under normal conditions of handling and use the use of CO_2 in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of CO_2 in air outside normal atmospheric ranges. It is on this basis that it is not necessary to submit additional genotoxicity data for CO_2 in terms of an *in vivo* test. [1]	Document III-A6 Section 6.6.4

Footnotes

1. It is not scientifically necessary, on the basis of the genotoxicity data available, to submit additional *in vivo* genotoxicity tests (the data requirements detailed in Document III-A 6.6.6).

3.7 CARCINOGENICITY

Route	Species Strain Sex no/group	Dose levels Frequency of application	Tumours	Remarks	Reference
N/A.	N/A	N/A	N/A	It is not considered scientifically necessary to determine the carcinogenic potential of CO_2[1] for a number of reasons including: 1. Under normal conditions of use, CO_2 in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of CO_2 in air outside normal atmospheric ranges. 2. The potential for exposure to CO_2 when it is manufactured and used as a rodenticide is minimal [redacted] 3. The maximum exposure limits for safe working conditions are well established for CO_2, and all of these exposure limits are in general agreement. The use of CO_2 in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of CO_2 in air outside normal atmospheric ranges, and this is well below these agreed maximum exposure limits for safe working conditions. As the objective of an animal test is to predict the toxicological effect in humans, then an established safe exposure limit based on human data takes precedence over animal data generated for the approximation of a theoretical safe value. 4. While it is possible to carry out a carcinogenicity study on CO_2, it will be technically very difficult, full of constraints and expensive. The body's metabolism and physiology are extremely sensitive to CO_2, levels and will adjust to any atmospheric changes. This effects the body's metabolism making it difficult to differentiate any observations on the test animal as a toxic effect of carbon dioxide itself, or as a secondary effect of the body's change in metabolism. Because of this, even if the carcinogenicity study was carried out, it is going to provide little useful data for the risk assessment.	Document III-A6 Section 6.7

Footnotes

1. For the same reasons detailed in the table above, it is not considered scientifically necessary to determine the chronic toxicity of carbon dioxide (the data requirements detailed in Document III-A 6.5).

3.8 REPRODUCTIVE TOXICITY

3.8.1 Teratogenicity (1 of 3)

Route of exposure	Test type Method guideline	Method	Species Strain Sex No/group	Exposure Period	Doses	Critical effects dams Foetuses	NO(A)EL Maternal toxicity	NO(A)EL Teratogenicity Embryotoxicity	Remarks	Reference
Inhalation Study 1 of 3	No set guideline followed. Refer to "method" for summary of methodology followed.	Pregnancy was calculated from the time observed-copulation occurred. The pregnant rats in groups of 2 were placed in a plastic chamber for a single 24-hour period, where they were exposed to a gas mixture containing 6% CO_2 with 20% O_2 and 74% N_2 (the teratogenic agent). The earliest day of exposure was the 5th day of pregnancy and the latest day was the 21st day.	Rats Sprague-Dawley Female 6-12 per group	Single 24 hour periods.	6% CO_2	See footnote #	Not reported.	NO(A)EL has not been established. However, study indicates adverse effects to young born under conditions of 6% CO_2	See footnote*	Document III-A6 Section 6.8.1

Footnotes

\# No maternal toxic effects reported. There were increased abnormalities (intraventricular septal changes). Note there was also an increase in skeletal abnormalities. There was a slight increase in perinatal mortality in the test group, and a lower frequency of male offspring. The average pup weight was 18.9% higher in the test litters. Whist the effects could have been attributable to carbon dioxide they might also be a response to low pH or to increased oxygen tension (secondary to hyperventilation cause by increased carbon dioxide).

* This study determines the effect of exposure to 6% CO_2 for single 24-hour periods during certain days of pregnancy on offspring of rats. While this study was not generated to modern, scientifically acceptable protocols, it gives an indication about the possible teratogenic effects of CO_2. This study, not withstanding it's deficiencies, as be used to support the teratogenic assessment of CO_2 because:

1. Under normal conditions of use, the use of carbon dioxide in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of carbon dioxide in the local room environment, outside normal atmospheric ranges.
2. The potential for exposure to carbon dioxide when it is manufactured and used as a rodenticide is minimal and any exposure would be well below the established occupational exposure limits set by a number of different regulatory authorities to set national, international and supranational maximum exposure limits for safe working conditions.
3. Objectives of toxicity testing include the prediction of possible toxicological effects in humans, the exposures at which these effects might occur and the mechanisms of action. However, as a maximum occupational exposure limit is already well established, and the limit set by a number of regulatory authorities is in general agreement, further toxicity testing is not considered scientifically necessary.

3.8.1 Teratogenicity (2 of 3)

Route of exposure	Test type Method guideline	Method	Species Strain Sex No/group	Exposure Period	Doses	Critical effects dams Foetuses	NO(A)EL Maternal toxicity	NO(A)EL Teratogenicity Embryotoxicity	Remarks	Reference
Inhalation 2 of 3	No set guideline followed. Refer to "method" for summary of methodology followed.	Rats were placed in a 9-litre desiccator with inlet and outlet valves to permit the continuous flow of gases. All gas mixtures contained 20% oxygen and were made up to 100% with nitrogen. Food and water were available in the treatment chamber and a granular desiccant was used to maintain low humidity.	Rats Wistar Male Total of 40 animals.	1,2,4 or 8h	0 (control), 2.5%, 5.0% or 10.0 % carbon dioxide.	See footnote #	Not reported.	NO(A)EL has not been established. However, study indicates adverse effects to male tesis tissue of rats exposed to 2.5% -10% carbon dioxide. The changes were positively associated with the concentration of carbon dioxide and the duration of treatment.	See footnote*	Document III-A6 Section 6.8.1

Footnotes

No maternal toxic effects reported. Treatment of rats with carbon dioxide at all levels employed (2.5% to 10%) caused a doubling of respiration rate, compared to controls exposed either to compressed air or to a gas mixture containing no carbon dioxide, but no other gross effects were noted. Neither the testis weight nor the weight of accessory glands was effected by the treatment. Histologically, testis tissue from treated rats exhibited changes that were positively associated with both the concentration of atmospheric carbon dioxide and the duration of treatment. After 4h of treatment with 2.5% carbon dioxide, however, intratubular relationships were observably disrupted. Sloughing of tubular components and lack of luminal definition were in evidence following treatment with 5% carbon dioxide for the same length of time. There was a progressive streaking and vacuolisation toward the basal membrane that occurred following exposure to 10% carbon dioxide, for 4h. These degenerative changes were typical of treated animals, and they occurred consistently. The most readily observable changes occurred with higher levels of carbon dioxide, as exposures were increased. However, further dramatic changes were not seen when exposure time was extended from 4 to 8h. Whist the effects could have been attributable to carbon dioxide they might also be a response to low pH or to increased oxygen tension (secondary to hyperventilation cause by increased carbon dioxide).

* This study determines the effect of exposure to 0 (control), 2.5%, 5.0% or 10.0 % carbon dioxide for 1,2,4 or 8h periods on the male testis tissue of rats. While this study was not generated to modern, scientifically acceptable protocols, it gives an indication about the possible teratogenic effects of CO_2. This study, not withstanding it's deficiencies, as be used to support the teratogenic assessment of CO_2 because:

1. Under normal conditions of use, the use of carbon dioxide in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of carbon dioxide in the local room environment, outside normal atmospheric ranges.
2. The potential for exposure to carbon dioxide when it is manufactured and used as a rodenticide is minimal and any exposure would be well below the established occupational exposure limits set by a number of different regulatory authorities to set national, international and supranational maximum exposure limits for safe working conditions.
3. Objectives of toxicity testing include the prediction of possible toxicological effects in humans, the exposures at which these effects might occur and the mechanisms of action. However, as a maximum occupational exposure limit is already well established, and the limit set by a number of regulatory authorities is in general agreement, further toxicity testing is not considered scientifically necessary.

3.8.1 Teratogenicity (3 of 3)

Route of exposure	Test type Method guideline	Method	Species Strain Sex No/group	Exposure Period	Doses	Critical effects dams Foetuses	NO(A)EL Maternal toxicity	NO(A)EL Teratogenicity Embryotoxicity	Remarks	Reference
Inhalation 3 of 3	No set guideline followed. Refer to "method" for summary of methodology followed.	See footnote **	Mice Swiss Male 10 mice /group.	Total: 6h (intermittent exposure over 8h) Total: 26.5 h (intermittent exposure over 6 d)	65%/35% mixture air/carbon dioxide.	See footnote #	Not reported.	NO(A)EL has not been established. However, study indicates adverse effects to the morphology of spermatozoa of mice, and their fertility when they were exposed to 35% carbon dioxide.	See footnote*	Document III-A6 Section 6.8.1

Footnotes

**In the experimental chamber, an air/carbon dioxide mixture in the proportion of 1.8/1.0 by volume (equivalent to 65%/35% mixture) was supplied. In winter (air temperature 18°C) mice survived if allowed to recuperate in air for 30 minutes after each 2h exposure to the mixture. In summer (air temperature 30 to 32°C) a recuperation period of 15 minutes was necessary after each hour of exposure. To test male fertility, males and virgin females, all of comparable body weights were allotted in equal numbers to a control and an experimental group. On the first day males were treated for 4h and kept away from the females. On each of the subsequent 5 days, they were treated for 4.5h before rejoining their mates at night. The pairs were separated each morning. There were 11 repetitions of the experiment ('trials') with fresh animals for each trial. To study the delayed effect of the treatment, the same males of the 5th, 6th and 8th to 11th trials were paired again with virgin females for 6 days starting 15 days after the end of the treatment. Litter size was recorded in 17 trials. Whist the effects could have been attributable to carbon dioxide they might also be a response to low pH or to increased oxygen tension (secondary to hyperventilation cause by increased carbon dioxide).

Exposure of male mice to a 1.8/1.0 mixture of air/carbon dioxide (equivalent to 65%/35% mixture) for a total of 6h reduced the area and breadth of the head and of the mid-piece of live spermatozoa in the vasa deferentia. During a total of 26.5 h exposure spread over six days, males when test-mated, had a low conception rate but the numbers of offspring in the litters produced were normal. The low conception rate appeared to persist even 15 days after the end of the treatment.

* This study determines the effect of exposure to 0 (control), 2.5%, 5.0% or 10.0 % carbon dioxide for 1,2,4 or 8h periods on the male testis tissue of rats. While this study was not generated to modern, scientifically acceptable protocols, it gives an indication about the possible teratogenic effects of CO_2. This study, not withstanding it's deficiencies, as be used to support the teratogenic assessment of CO_2 because:

1. Under normal conditions of use, the use of carbon dioxide in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of carbon dioxide in the local room environment, outside normal atmospheric ranges.
2. The potential for exposure to carbon dioxide when it is manufactured and used as a rodenticide is minimal and any exposure would be well below the established occupational exposure limits set by a number of different regulatory authorities to set national, international and supranational maximum exposure limits for safe working conditions.
3. Objectives of toxicity testing include the prediction of possible toxicological effects in humans, the exposures at which these effects might occur and the mechanisms of action. However, as a maximum occupational exposure limit is already well established, and the limit set by a number of regulatory authorities is in general agreement, further toxicity testing is not considered scientifically necessary.

3.8.2 Fertility

Route of exposure	Test type Method guideline	Species Strain Sex No/group	Exposure Period	Doses	Critical effect	NO(A)EL Parental		NO(A)EL FI		NO(A)EL F2		Remarks	Reference
						m	f	m	f	m	F		
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable		Not applicable		Not applicable		See footnote*	Document III-A6 Section 6.8.2

Footnote

* It is not considered necessary to determine the reproductive effects of CO_2 for a number of reasons including:

1. Under normal conditions of use, the use of CO_2 in Rentokil Initial's rodenticide (PT14) products will not cause elevation in the level of CO_2 in air outside normal atmospheric ranges.
2. The potential for exposure to CO_2 when it is manufactured and used as a rodenticide is minimal [redacted] CO_2 is intended for use in a rodenticide product called Radar. Radar involves the use of 3g CO_2 in an aerosol canister. The use of CO_2 in an aerosol means that there is no primary exposure to the operator - the only potential exposure occurs when the rodenticide unit is tripped by a rodent, and the CO_2 is released from the aerosol canister to kill the animal. [redacted]
3. The maximum exposure limits for safe working conditions are well established for CO_2, and all of these exposure limits are in general agreement. The use of CO_2 in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of CO_2 in air, outside normal atmospheric ranges and this is well below these agreed maximum exposure limits for safe working conditions. As the objective of an animal test is to predict the toxicological effect in humans, then an established safe exposure limit based on human data takes precedence over animal data generated for the approximation of a theoretical safe value.
4. While it is possible to carry out a multigeneration study on CO_2, it will be technically very difficult, full of constraints and expensive. The body's metabolism and physiology are extremely sensitive to CO_2, levels and will adjust to any atmospheric changes. This affects the body's metabolism making it difficult to differentiate any observations on the test animal as a toxic effect of carbon dioxide itself, or as a secondary effect of the body's change in metabolism as it adjusts to the change in atmospheric CO_2 levels. Because of this, even if the multigeneration study was carried out, it is not going to provide any useful data for the risk assessment.

3.9 NEUROTOXICITY

Remark	Reference
There is a substantial volume of data available on the toxicity of carbon dioxide, and none of it indicates that carbon dioxide may have neurotoxic effects. It is on this basis that it is not necessary to submit additional toxicity data about the neurotoxicity of carbon dioxide.	Document III-A6 Section 6.9

3.10 HUMAN DATA

Effects of excessive carbon dioxide exposure in man are well reported in the product literature. These studies have been summarised in Document IIIA Section 6.1.3, 6.4.3, 6.5 and 6.12. The key results for man include the following:

Exposure to 1% carbon dioxide (time weighted average) during the working day has little effect on blood parameters, including bicarbonate and carbon dioxide. (It should be noted that the author of the study had great difficulty in monitoring the exposure of subjects to carbon dioxide because of their movements).

Exposure to 1.5% carbon dioxide led to lower heart rate, reduced tolerance to vigorous exercise. There was no apparent changes in performance or basic physiological parameters when humans were exposed to 1.5% carbon dioxide for 42 days. There was slight acidosis for 23 days, increased respiratory rate and increased systolic BP.

Exposure to 3% carbon dioxide leads to deeper breathing, headache, reduced hearing ability, increased heart rate and acidosis.

At 5-10% carbon dioxide, in addition to the effects detailed for exposure to 3% carbon dioxide there is more laborious breathing and loss of judgement.

At 10% carbon dioxide , in addition to the symptoms detailed for 5-10% carbon dioxide, there is also loss of consciousness.[7]

It has been widely reported that the effects associated with carbon dioxide exposure are reversible once the carbon dioxide has been removed.

It should be noted that under normal conditions of use, the use of carbon dioxide in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of carbon dioxide in air, outside normal atmospheric ranges, and the studies available on man tend to address much longer periods of exposure than are likely to be relevant for the use of carbon dioxide in the representative product, Radar.

3.11 OTHER TOXICOLOGICAL EFFECTS

Remark	Reference
There is a substantial volume of data available on the toxicity of carbon dioxide, and none of it indicates that carbon dioxide is of sufficient concern to justify further investigation by a mechanistic study, or by routes of administration that are not considered in the core toxicity data set. In addition, carbon dioxide is not mixed or added to any other chemicals during it's normal use so it is not necessary to provide data on degradation products, by-products and reaction products relating to the human exposure to carbon dioxide.	Document III-A6 Section 6.10 Document III-A6 Section 6.11 Document III-A6 Section 6.14
It is not necessary to submit data to consider the toxicity of carbon dioxide in food or feeding stuffs because carbon dioxide is not intended for use in areas where there will be contamination of food or feeding stuffs. Carbon dioxide is also not intended for use directly on plants, making it unnecessary to consider the toxic effect of metabolites from treated plants.	Document III-A6 Section 6.15 Document III-A6 Section 6.16
It should be noted that there is a low level of exposure expected from the use of carbon dioxide in Rentokil Initial's (PT 14) products because under normal conditions of use, the use of carbon dioxide in Rentokil Initial's (PT 14) products will not cause any elevation in the level of carbon dioxide in air outside normal atmospheric ranges.	Document III-A6 Section 6.17

Table 4-2: Standard form for justification of the non-submission of data

Section 7.1.1.1.1 **Annex Point/TNsG** **Annex IIA, VII.7.6.2.1**	**Hydrolysis as a function of pH and identification of breakdown products** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *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:	Further work or studies are not considered to be scientifically justified as the chemistry of carbon dioxide is well known and this result can be predicted from the intrinsic properties of carbon dioxide. Carbon dioxide is moderately soluble in water and at 20°C, 88ml of carbon dioxide will dissolve in 100ml of water. Some of this dissolved carbon dioxide will react with water to form carbonic acid. $CO_2 + H_2O \leftrightarrow H_2CO_3$ The equilibrium constant for this reaction is: $K=[CO_2] / [H_2CO_3] \approx 600.$ This means that there is around 600 times more of the carbon dioxide present in solution than is actually converted to carbonic acid. This un-degraded carbon dioxide will not degrade any further within this system. Carbonic acid is a weak acid that will dissociate further to produce the bicarbonate ion and water. $H_2CO_3 + OH^- \leftrightarrow HCO^-_3 + H_2O$ The bicarbonate ion can further dissociate to produce the carbonate ion and water. $HCO^-_3 + OH^- \leftrightarrow CO_3^{2-} + H_2O$ In summary, carbon dioxide is soluble in water. A small percentage of the dissolved carbon dioxide will be present as carbonic acid. Carbonic acid will undergo further reactions to produce bicarbonate and carbonate ions. Thus, an aqueous solution of carbon dioxide will contain mainly carbon dioxide, with a small amount of carbonic acid, bicarbonate ions and carbonate ions. No further reactions will take place in the absence of other chemicals. Continued...	

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

Detailed justification: (continued):	In addition, it should be noted that each of these reactions is reversible and equilibrium will exist for each. The introduction or removal of even tiny amounts of any of the above chemical species into the system will cause the equilibria to be disturbed and change the concentrations of all the above species to change. For this reason, it would be necessary to conduct the experiment in a sealed system with some sort of in-built analysis capability for whichever of the ions are to be monitored. The concentration of these ions is likely to be so low that they cannot accurately be measured without removing them from the system and thus disturbing the equilibria. Provided there are no other chemicals present, no further reactions will take place. As the dissociation reactions produce hydrogen ions, these will be favoured less in acidic solutions, the result being that the bicarbonate and carbonate ions will be formed less favourably than in basic solutions. As stated above, there is 600 times more carbon dioxide in solution than is converted to carbonic acid. This will not change with time and so carbon dioxide can be considered to be ***hydrolytically stable.***
Undertaking of intended data submission [ ]	Not applicable

[redacted]

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

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

Table 4-2: Standard form for justification of the non-submission of data

Section 7.1.1.1.2 **Annex Point/TNsG** **Annex IIA, VII.7.6.2.2**	**Phototransformation in water including identity of the products of transformation** 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**	[4]	**Scientifically unjustified**	[ ]
Limited exposure	[ ]	**Other justification**	[ ]		

Detailed justification:

The US EPA method entitled Fate, Transport and Transformation Test Guidelines - OPPTS 835.2210 - Direct Photolysis Rate in Water by Sunlight., states that the method is applicable to all chemicals which have UV/visible absorption maxima in the range of 290nm to 800nm.

Carbon dioxide has a UV absorption maxima of [redacted] and as such, this test is technically not feasible to perform.

Should photolysis be an issue (which it is not), the only products of transformation would be carbonic acid, bicarbonate ions and carbonate ions as detailed below.

Carbon dioxide is moderately soluble in water and at 20°C, 88ml of carbon dioxide will dissolve in 100ml of water. Some of this dissolved carbon dioxide will react with water to form carbonic acid.

$CO_2 + H_2O \leftrightarrow H_2CO_3$

The equilibrium constant for this reaction is: $K=[CO_2] / [H_2CO_3] \approx 600$.

This means that there is around 600 times more of the carbon dioxide present in solution than is actually converted to carbonic acid. This un-degraded carbon dioxide will not degrade any further within this system. Carbonic acid is a weak acid that will dissociate further to produce the bicarbonate ion and water.

$H_2CO_3 + OH^- \leftrightarrow HCO^-_3 + H_2O$

The bicarbonate ion can further dissociate to produce the carbonate ion and water.

$HCO^-_3 + OH^- \leftrightarrow CO_3^{2-} + H_2O$

Continued....

Section 7.1.1.1.2 **Annex Point/TNsG** **Annex IIA, VII.7.6.2.2**	**Phototransformation in water including identity of the products of transformation** Section 7: Ecotoxicological Profile, including Fate and Behaviour

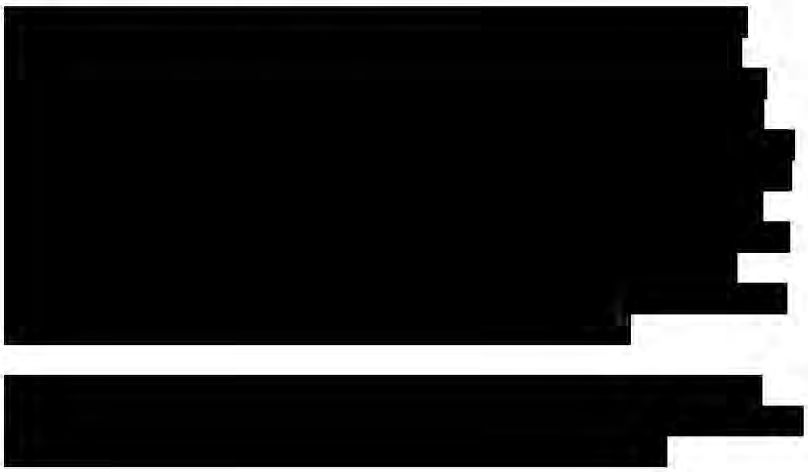
Detailed justification: (continued):	In summary, carbon dioxide is soluble in water. A small percentage of the dissolved carbon dioxide will be present as carbonic acid. Carbonic acid will undergo further reactions to produce bicarbonate and carbonate ions. Thus, an aqueous solution of carbon dioxide will contain mainly carbon dioxide, with a small amount of carbonic acid, bicarbonate ions and carbonate ions. No further reactions will take place in the absence of other chemicals. [redacted]
Undertaking of intended data submission [ ]	Not applicable

[redacted]

Section 7.1.1.1.2 **Annex Point/TNsG**	**Phototransformation in water including identity of the products of transformation**

	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	

Table 4-2: Standard form for justification of the non-submission of data

Section 7.1.1.2.1 **Annex Point/TNsG** **Annex IIA, VII.7.6.1.1**	**Ready biodegradability** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [**4**]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	Carbon dioxide does break down in water to give carbonic acid : $CO_2 + H_2O \leftrightarrow H_2CO_3$ This however, is not brought about by biological means, as it will happen as the result of simple dissolution of the carbon dioxide in water. Testing for the ready biodegradability of carbon dioxide is scientifically unjustified. Carbon dioxide evolution is one of the major end points used in such biodegradability tests. Ready biodegradability describes the conversion of test substances to carbon dioxide; thus recognising that there will not normally be any further degradation. 	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.1.1.2.1 Annex Point/TNsG Annex IIA, VII.7.6.1.1	**Ready biodegradability** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

Section A7.1.1.2.1 **Biodegradability (Ready)**
Annex Point IIA, VII, 7.6.1.1 Section 7: Fate and Behaviour in the Environment

			Official use only
		1. REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2			
1.2.3	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No. Not carried out to EC Method C4, E .in Annex V of Directive 67/548/EEC.	
2.2	**GLP**	No. No record of study being conducted in compliance with the requirements of GLP.	
2.3	**Deviations**	Yes. No set guideline followed.	
		3. MATERIALS AND METHODS	
3.1	**Test material**	As given in section 2.	
3.1.1.	Lot/Batch number	Not reported.	
3.1.2	Specification	[redacted]	
3.2	**Reference substance**	No.	
3.2.1	Initial concentration of reference substance	Not used.	

3.3	**Testing procedure**	
3.3.1	Inoculum/ test species	See table A7_1_1_2-1, at the end of this study summary for description of sample sites. Refer to section 5.1 Materials and Methods for details of analysis undertaken.
3.3.2	Test system	See table A7_1_1_2-1, at the end of this study summary for description of sample sites. Refer to section 5.1 Materials and Methods for details of analysis undertaken.
3.3.3	Test conditions	See table A7_1_1_2-1, at the end of this study summary for description of sample sites. Refer to section 5.1 Materials and Methods for details of analysis undertaken.
3.3.4	Method of preparation of test solution	<u>For pH and alkalinity determination</u> Unfiltered stream water samples were collected, by sealing bottles under water to prevent exposure to the atmosphere, placed on ice, returned to the laboratory and refrigerated until analysis. <u>For determination of solute concentration</u> Initial samples were taken at beginning of the study to determine solute concentration. Samples for solute analysis were filtered in the field using a Gelman type A/E glass fibre filter, placed on ice, returned to the laboratory and refrigerated until analysis. Samples were analysed for N and P within 4 days of collection. Samples for cation analysis were preserved with 0.5% high purity HNO_3 and cation and anion samples were analysed within 4 months of collection. <u>Water temperature and specific conductance</u> These measurements were taken in the field using the Orion Model 122.
3.3.5	Initial TS concentration	Carbon dioxide concentration in samples taken from the Oak Ridge National Environmental Research Park varied from 3340 ppmv in Spring to 9927 ppmv in Summer (9.3 and 28 times atmospheric equilibrium respectively). Carbon dioxide concentration in samples taken from the Great Smoky Mountains National Park increased from 5340 ppmv in Spring to 8565 ppmv in Summer (15 times and 24 times atmospheric equilibrium respectively). Carbon dioxide concentration in samples taken along Little Pigeon River and Little River (60 km stretches corresponding to increasing in basin size from 1.7 to 477 km^2 in the Little Pigeon River and 2.5 to 275 km^2 in the Little River), decreased ca. 50% along the river. *See table A7_1_1_2-1, at the end of this study summary for description of sample sites.*

3.3.6	Duration of test	Approximately 6 months for Oak Ridge National Environmental Research Park and Great Smoky Mountains National Park (for the studies to determine effect of catchment geomorphology and ground water flow paths and effects of soil organic matter (elevational gradient) respectively). A single sample collection was taken at the Little Pigeon River and Little River site (study examine the effects of drainage basin area and stream size on partial pressure of carbon dioxide in streams). *For full description of test sites, and dates samples were taken see table A7_1_1_2-1, at the end of this study summary.*
3.3.7	Analytical parameter	Carbon dioxide concentration in stream water was calculated from water alkalinity (measured by titration).
3.3.8	Sampling	See table A7_1_1_2-1, at the end of this study summary for description of sample sites, number of samples taken and dates.
3.3.9	Intermediates/ degradation products	Not applicable. Carbon dioxide evolution is one of the major end points used in biodegradability tests. Biodegradability describes the conversion of test substances to carbon dioxide, thus recognising that there will not normally be any further degradation.
3.3.10	Nitrate/nitrite measurement	Not reported.
3.3.11	Controls	Not reported.
3.3.12	Statistics	The effects of geology and season on pH, alkalinity and gas partial pressures were assessed with two-way analysis of variance. Following an initial test for homeogeneity of slopes, analysis of co-variance was used to evaluate seasonal differences in data from the Great Smoky Mountains National Park survey and differences between the Little Pigeon River and Little River (elevation and longitudinal location used as covariates). Elevation and longitudinal effects were analysed with linear regression. Data for linear regressions were pooled if results from analysis of covariance results were non-significant ($p \geq 0.05$)
		4 RESULTS
4.1	**Degradation of test substance**	
4.1.1	Graph	Not applicable. Carbon dioxide evolution is one of the major end points used in biodegradability tests. Biodegradability describes the conversion of test substances to carbon dioxide, thus recognising that there will not normally be any further degradation.
4.1.2	Degradation	Not applicable. Refer to 4.1.1 above for explanation.
4.1.3	Other observations	<u>Effects of geomorphology and subsurface flowpaths on partial pressure of carbon dioxide in streams: Oak Ridge National Environmental Research Park Survey</u> pH in streams of the Oak Ridge National Environmental Research Park ranged from 7.32 to 8.95 but was not significantly related with catchment geology ($p = 0.751$) or sampling date ($p = 0.120$), but the pH was significantly greater in summer than spring, averaging (Continued....)

4.1.3	Other observations (Continued)	5155 and 2663 µEq/L respectively ($p < 0.001$). Based upon the ion concentrations measured on the first sampling date, carbonate alkalinity was strongly correlated with total alkalinity (linear regression $r^2 = 1.000$, $p < 0.001$). The equation for the line describing the relationship between carbonate and total alkalinity has a slope of 0.976 indicating that the most acid neutralising capacity was from carbonates and carbon dioxide partial pressures were overestimated by only 2.4%. Carbon dioxide partial pressures did not differ significantly with catchment geology ($p = 0.602$). However, mean carbon dioxide partial pressures increased three fold from 3340 to 9927 ppmv as stream temperatures increased from 12.3°C in the spring to 16.1°C during summer ($p = 0.004$). These partial pressures translate to saturations relative to atmospheric equilibrium (pCO_2 (equilib); assuming atmospheric pCO_2 of 360 ppmv), of 9.3 and 28 in Spring and Summer respectively. <u>Effects of soil organic matter (elevational gradient) on partial pressure of carbon dioxide in streams: Great Smoky Mountains National Park survey</u> In the Great Smoky Mountains National Park, pH did not vary between sample dates ($p = 0.557$) but declined with elevation ($p < 0.001$). pH in streams below 800m averaged 6.45 but declined to a mean of 5.72 above 1200 m. Similarly, alkalinity exhibited an elevation gradient ($p < 0.001$), declining from as much as 484 µEq/L at 488 m to only 6 µEq/L at 1061 m. Alkalinity also differed between sampling dates ($p = 0.023$) averaging 130 µEq/L in spring compared with 185 µEq/L in summer. The correlation between carbonate and total alkalinity was much reduced compared to that observed in the Oak Ridge Survey (details above) ($r^2 = 0.443$, $p < 0.001$, with a slope of 0.610 indicating greater uncertainty, and overestimates of carbon dioxide partial pressures by as much as 39%. As in study to determine the effects of geomorphology and subsurface flowpaths on partial pressure of carbon dioxide in streams (the Oak Ridge Survey), partial pressures of carbon dioxide in streams at the Great Smoky Mountains National Park, did not vary with elevation ($p = 0.368$). Partial pressure of carbon dioxide, however, did increase seasonally from a mean of 5340 ppmv (pCO_2 (equilib) = 15) in Spring mean stream temperature = 8.4°C) to 8565 ppmv (pCO_2 (equilib) = 24, mean stream temperature = 14.3°C) in Summer ($p < 0.001$). <u>Effects of drainage basin area and stream size on partial pressure of carbon dioxide in streams (longitudinal trends).</u> pH rose with distance from headwaters ($r^2 = 0.88$, $p = <0.001$), increasing from ca. 6.40 in headwater streams to 7.96 65 km downstream. Similarly, alkalinity increased from as low as 68 µEq/L in headwaters to as high as 2022 µEq/L at downstream sites ($p < 0.001$). As in the study to determine the effects of geomorphology and subsurface flowpaths on partial pressure of carbon dioxide in streams (the Oak Ridge Survey), nearly all alkalinity was attributable to carbonates (slope = 0.989, $r^2 = 1.00$, $p < 0.001$), producing over estimates of carbon dioxide partial Continued...

4.1.4	Other observations (Continued)	pressures by only 1.1%. In contrast to a lack of spatial variation in the carbon dioxide partial pressure in the previous two surveys, carbon dioxide partial pressure declined along the Little Pigeon River and the Little River (p = 0.031) although carbon dioxide partial pressure did not differ between rivers (p = 0.806). In headwaters carbon dioxide partial pressure ranged from 2905 to 3454 ppmv (pCO_2 (equilib) = 8.1 to 9.6) but declined ca. 50% to <2000 ppmv (pCO_2 (equilib) < 5.6) 63 km downstream.
4.1.4	Degradation of TS is abiotic control	Not applicable. Refer to 4.1.1 above for explanation.
4.1.5	Degradation of reference substance	Reference substance not used.
4.1.6	Intermediates/ degradation products	Not applicable. Refer to 4.1.1 above for explanation.
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and Methods**	This study was not carried out to Guideline C4 E in Annex V of Directive 67/548/EEC. Using gas content of stream water, factors regulating ecosystem metabolism were investigated in different catchment. Specifically, three surveys were conducted to examine how ecosystem metabolism was affected by: 1) Catchment geomorphology and ground water flow paths 2) Soil organic matter storage 3) Drainage basin area and stream size. See table A7_1_1_2-1, at the end of this study summary for description of sample sites, number of samples taken and dates. <u>For pH and alkalinity determination</u> Unfiltered stream water samples were collected, by sealing bottles under water to prevent exposure to the atmosphere, placed on ice, returned to the laboratory and refrigerated until analysis. pH and alkalinity were measured with a Fisher autotitrator model 380/381 equipped with an Orion Ross pH electrode (precision of pH = +/- 0.01 units). Alkalinity was determined by potentiometric titration to fixed end points of 4.5 and 4.2 using 0.01 N HCl (precision = +/- 10µEq/L). Concnetrtaions of Al, B, Ba, Ca, Fe, Mg, Na, Si and Sr were measured by inductively copuled plasma emission spectroscopy and K by atomic adsorption spectrometry. Concentrations of SO_4^{2-} and Cl- were measured by ion chromatraphy. Soluble reactive phosphorus (SRP) was measured by the ascorbic acid method. Samples were analysed manually with a 10 cm spectrophotometer cuvette to achieve low analytical detection limit (0.5 µgP/L) and high precision (+/-0.4 µgP/L). NH_4+ was measured by automated phenate colorimetry (detection limit = 2 µgN/L, precision +/- 0.5 µgN/L). The proportion of total alkalinity (as determined by potentiometric titration) derived from carbonate alkalinity was assessed from solute chemistry and alkalinity using PHREEQC. Continued....

Section A7.1.1.2.1 **Biodegradability (Ready)**
Annex Point IIA, VII, 7.6.1.1 Section 7: Fate and Behaviour in the Environment

5.1	**Materials and Methods** (Continued)	Carbon dioxide partial pressure was calculated from alkalinity (measured by titration) and pH, and was corrected for ionic strength. The disassociation constants K_H K_1 and K_2 were corrected for temperatures using standard equations. The precision of carbon dioxide partial pressure estimates varied primarily as a function of alkalinity, ranging from +/-10, 6, 3 and 2% at alkalinities of 50, 100, 500 and 6000 µEq/L respectively. For determination of solute concentration Initial samples were taken at beginning of the study to determine solute concentration. Samples for solute analysis were filtered in the field using a Gelman type A/E glass fibre filter, placed on ice, returned to the laboratory and refrigerated until analysis. Samples were analysed for N and P within 4 days of collection. Samples for cation analysis were preserved with 0.5% high purity HNO_3 and cation and anion samples were analysed within 4 months of collection. Water temperature and specific conductance These measurements were taken in the field using the Orion Model 122.
5.2	**Results and discussion**	Carbon dioxide partial pressure in streams is not related to catchment geomorphology. The overall rate of ecosystem respiration may be more closely coupled to climate. Stream water carbon dioxide partial pressure is also not related to elevation (and presumably soil organic matter storage), although estimates of carbon dioxide partial pressure in the Great Smoky Mountains National Park survey had considerable uncertainty given the low correlation between carbonate and total alkalinity observed on the first sampling date. The lack of relationship between elevation and carbon dioxide partial pressure suggests that other factors such as climate are controlling the overall rate of decomposition. Streams are typically supersaturated with carbon dioxide, relative to the atmosphere with pCO_2 (equilib) commonly ranging from 2 to 10, and in some streams as high as 50 to 100 pCO_2 (equilib). Stream water carbon dioxide partial pressure is governed by instream decomposition of organic matter, diffusive exchange with the atmosphere, and ground water inputs. In one of the streams sampled in the Oak Ridge survey (the West Fork of Walker Branch), a sizable portion of carbon dioxide in surface water appears to come from groundwater inputs. In a previous study, the carbon dioxide partial pressure in ground water discharging into Walker Branch averaged 3160 ppmv (over two fold greater than the mean carbon dioxide partial pressure concentration of 1560 ppmv in the stream. Groundwater carbon dioxide originates from soils where the concentration is elevated due to root respiration and heterotrophic oxidation of detritus. Soil respiration, in turn is potentially governed by organic matter quantity and quality, and oxygen although temperature and soil moisture appear to be the dominant controls. The coupling between temperature and respiration results in the distinct seasonal pattern of soil carbon dioxide (with a summer high and a winter low). These seasonal

Continued....

Section A7.1.1.2.1 **Biodegradability (Ready)**
Annex Point IIA, VII, 7.6.1.1 Section 7: Fate and Behaviour in the Environment

5.2	**Results and discussion**	patterns of soil carbon dioxide have been shown to influence stream water chemistry. In White Oak Run, located in the Shenandoah National Park, Virginia (a region with climate similar to the sites detailed in this study) bicarbonate in stream water closely tracked soil carbon dioxide probably due to weathering of parent material by dissolved carbon dioxide produced by respiration in soils. Similarly, in the present study, temperature appears to be an important factor regulating stream water carbon dioxide partial pressure. Geomorphology and soil organic matter storage had no effect on stream carbon dioxide partial pressure, but gas levels increased from Spring to Summer. Lakes are commonly superaturated with carbon dioxide, relative to the atmosphere and function as conduits for carbon dioxide transport from terrestrial ecosystems to the atmosphere. The streams examined in this study were also supersaturated with pCO_2 (equilib) 3.5 to 48 (median = 13). Thus, like lakes, streams function as conduits for gas exchange to the atmosphere. In headwater streams where groundwater discharge is relatively high, much of this gas likely comes from the catchment. With incrwasing river size, however, riparian or instream gas generation becomes more important. All catchments primarily emitted carbon dioxide, large basins or those dominated by shallow hydrologic flowpaths or high soil organic matter content emitted a greater proportion of respiratory end points as methane.
5.3	**Conclusion**	Natural levels of carbon dioxide found in water are above those measured in the atmosphere, ranging from 9 x atmospheric concentration in Spring and 24 times atmospheric concentration in the Summer.
5.3.1	Reliability	3
5.3.2	Deficiencies	Yes. This study was not carried out to Guideline C4 E in Annex V of Directive 67/548/EEC. Rather than looking at ready biodegradability of carbon dioxide *per se,* this study determines the normal background levels of carbon dioxide found in aquatic ecosystems. It should be noted that the use of carbon dioxide by Rentokil Initial would not increase the normal atmospheric concentrations of carbon dioxide in the locality.

Table A7_1_1_2-1 Description of test sites

Criteria			
Study name	Effect of catchment geomorphology and ground water flow paths	Effects of soil organic matter	Effects of drainage basin area and stream size
Site name	Oak Ridge National Environmental Research Park	Great Smoky Mountains National Park	Little Pigeon River and Little River.
Description of site	Bedrock of this area is composed predominately of either shale or dolomite, oriented in parallel bands that form Northeast-southwest trending ridges. Geomorphology and hydrology of drainage basins are influenced by geology with shale catchments having shallower soils, broader unconstrained valley floors and more rapid hydrologic response times compared with dolomite catchments.	The elevation of sampling sites ranged from 525 to 1700 m and catchment areas varied from 0.07 to 7.81 km^2. The area consists of Precambrian metasedimentary rock, mostly quartzite and phylliye which is relatively resistant to weathering and provides little neutralisation capacity. Outcropping of a pyritic carbonaceous phyllite, the Anakeesta Formation, occur at higher elevations.	Eastern Tennessee, USA. Headwaters of both rivers are in the Great Smoky Mountains National Park, and the study reaches extend into the Tennessee River Valley where enviornmental conditions are the same as Oak Ridge National Environmental Research Park. Headwater reaches were < 2m wide, where downstream channels were 30-50 m wide.
Climate at test site	Typical of the humid southern Appalachian Region, with mean annual temperatures of 14.5°C, and mean annual precipitation of 140 cm.	Humid with mean annual precipitation of ca. 220 cm.	Headwaters of both rivers are in the Great Smoky Mountains National Park, and the study reaches extend into the Tennessee River Valley where enviornmental conditions are the same as Oak Ridge National Environmental Research Park.
Vegetation at test site	Vegetation is second-growth deciduous forest dominated by oak and hickory, with scattered pines on some ridges and mesophytic hardwoods such as tulip poplar and beech in valleys. The Research Park has been largely undisturbed since 1940. Land use before that was a mixture of row-crop agriculture, pasture and wood lots.	Soils are poorly developed, rich in organic matter and acidic. Vegetation is dominated by mature stands of red spruce and fraser fir at high elevation, with beech and hemlock becoming important at lower elevations and in Riparain zones. Rhododendron is abundant forming a dense subcanopy at high elevations and near stream channels at all elevations. The topography is steep with streams flowing in deeply incised valleys.	Headwaters of both rivers are in the Great Smoky Mountains National Park, and the study reaches extend into the Tennessee River Valley where enviornmental conditions are the same as Oak Ridge National Environmental Research Park.
Number of sampling sites	A total of ten headwater streams (n= 5 on each ridge type, catchment areas < 1.2 km^2) located within a 40 km^2 area were sampled	The effects of soil organic matter was explored by sampling 24 streams along an elevational gradient where soil organic matter storage increases with elevation.	Samples were taken along 46 and 65 km reaches of the Little Pigeon River and Little River respectively. Catchment area increased from 1.7 to 477 km^2 in the Little Pigeon River and 2.5 to 275 km^2 in the Little River from Headwater to downstream sampling stations.

Dates samples taken	30 March 1995, 7 September 1995	25th April 1995 and 15 September 1995.	Single sample collection on 21 June 1995.

Section A7.1.1.2.1 **Biodegradability (Ready)**
Annex Point IIA, VII, 7.6.1.1 Section 7: Fate and Behaviour in the Environment

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 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	Other conclusions: *(adopt applicant's version or include revised version)*
Reliability	*Based on 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 if 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 4-2: Standard form for justification of the non-submission of data

Section 7.1.1.2.2 **Annex Point/TNsG** **Annex IIA, VII.7.6.1.2**	**Inherent biodegradability** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *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** [4] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	Inherent biodegradability is technically not feasible to perform on carbon dioxide as the test methods are designed to work with water-soluble, non-volatile organic substances. Carbon dioxide, although being water-soluble, is volatile and inorganic.	
Undertaking of intended data submission [ ]	Not applicable.	

[redacted]

Section 7.1.1.2.2 Annex Point/TNsG Annex IIA, VII.7.6.1.2	**Inherent biodegradability** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	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	

Table 4-2: Standard form for justification of the non-submission of data

Section 7.1.1.2.3 **Annex Point/TNsG** **Annex IIIA, XII.2.1**	**Biodegradation in seawater** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *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:	Biodegradation in seawater is not required as carbon dioxide is not intended to be either used or released into marine environments. For these purposes, it is intended that CO_2 be used as a biocide in a closed system.	
Undertaking of intended data submission [ ]	Not applicable.	

[redacted]

	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	

Table 4-2: Standard form for justification of the non-submission of data

Section 7.1.2 **Annex Point/TNsG** **Annex IIIA, XII.2.1**	**Rate and route of degradation in aquatic systems including identification of metabolites** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [✔] **Scientifically unjustified** [✔]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	This testing of the degradation of carbon dioxide in aquatic systems is scientifically unjustified on the following basis: 1. Carbon dioxide does break down in water to give carbonic acid : $CO_2 + H_2O \leftrightarrow H_2CO_3$ This however, is not brought about by biological means, as it will happen as the result of simple dissolution of the carbon dioxide in water. 2. Testing for the ready biodegradability (A7.1.1.2.1) of carbon dioxide is also scientifically unjustified. Carbon dioxide evolution is one of the major end points used in such ready biodegradability tests. Ready biodegradability describes the conversion of test substances to carbon dioxide; thus recognising that there will not normally be any further degradation. 3. Inherent biodegradability (A7.1.1.2.2) is technically not feasible to perform on carbon dioxide as the test methods are designed to work with water-soluble, non-volatile organic substances. Carbon dioxide, although being water-soluble, is not non-volatile and is not organic.	
Undertaking of intended data submission [ ]	Not applicable.	

[redacted]

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

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

Table 4-2: Standard form for justification of the non-submission of data

Section A7.1.2.1.1 **Annex Point/TNsG** **Annex IIIA, XI.-2.1**	**Biological sewage treatment – aerobic biodegradation** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [✓]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [ ]	
Detailed justification:	Aerobic biodegradation in biological sewage treatment is not applicable here, as the carbon dioxide is not intended to enter a sewage treatment plant before release to the environment. For these purposes, it is intended that CO_2 be used as a biocide in a closed system.	
Undertaking of intended data submission [ ]	Not applicable.	

[redacted]

	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	

Table 4-2: Standard form for justification of the non-submission of data

Section A7.1.2.1.2 **Annex Point/TNsG** **Annex IIIA, XII.2.1**	**Biological sewage treatment - anaerobic biodegradation** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [✓]	**Other justification** [ ]	
Detailed justification:	Anaerobic biodegradation is not applicable here, as the carbon dioxide is not intended to be exposed to anaerobic conditions. For these purposes, it is intended that CO_2 be used as a biocide in a closed system.	
Undertaking of intended data submission [ ]	Not applicable.	

[redacted]

	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	

Table 4-2: Standard form for justification of the non-submission of data

Section 7.1.2.2.1 **Annex Point/TNsG** **Annex IIIA, XII.2.1**	**Biodegradation in freshwater – Aerobic aquatic degradation study** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [✓] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	This testing of the degradation of carbon dioxide in aquatic systems is scientifically unjustified on the following basis: 1. Carbon dioxide does break down in water to give carbonic acid : $CO_2 + H_2O \leftrightarrow H_2CO_3$ This however, is not brought about by biological means, as it will happen as the result of simple dissolution of the carbon dioxide in water. 2. Testing for the ready biodegradability (A7.1.1.2.1) of carbon dioxide is also scientifically unjustified. Carbon dioxide evolution is one of the major end points used in such ready biodegradability tests. Ready biodegradability describes the conversion of test substances to carbon dioxide; thus recognising that there will not normally be any further degradation. 3. Inherent biodegradability (A7.1.1.2.2) is technically not feasible to perform on carbon dioxide as the test methods are designed to work with water-soluble, non-volatile organic substances. Carbon dioxide, although being water-soluble, is not non-volatile and is not organic.	
Undertaking of intended data submission [ ]	Not applicable.	

[redacted]

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

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

Table 4-2: Standard form for justification of the non-submission of data

Section 7.1.2.2.2 **Annex Point/TNsG** **Annex IIIA, XII.2.1**	**Biodegradation in freshwater – water/sediment degradation study** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [✓] **Scientifically unjustified** [✓]	
Limited exposure [✓]	**Other justification** [ ]	
Detailed justification:	The testing of the degradation of carbon dioxide in aquatic systems is scientifically unjustified because carbon dioxide, under normal conditions of use in Rentokil Initial's rodenticide (PT14) products will not be applied directly or indirectly to the sediment in aquatic system. In addition: 1. Carbon dioxide does break down in water to give carbonic acid : $CO_2 + H_2O \leftrightarrow H_2CO_3$ This however, is not brought about by biological means, as it will happen as the result of simple dissolution of the carbon dioxide in water. 2. Testing for the ready biodegradability (A7.1.1.2.1) of carbon dioxide is also scientifically unjustified. Carbon dioxide evolution is one of the major end points used in such ready biodegradability tests. Ready biodegradability describes the conversion of test substances to carbon dioxide; thus recognising that there will not normally be any further degradation. 3. Inherent biodegradability (A7.1.1.2.2) is technically not feasible to perform on carbon dioxide as the test methods are designed to work with water-soluble, non-volatile organic substances. Carbon dioxide, although being water-soluble, is volatile and inorganic.	
Undertaking of intended data submission [ ]	Not applicable.	

[redacted]

Section 7.1.2.2 Annex Point/TNsG Annex IIIA, XII.2.1	**Biodegradation in freshwater – water/sediment degradation study** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

Table 4-2: Standard form for justification of the non-submission of data

Section 7.1.3 **Annex Point/TNsG** **Annex IIIA, XII, 2.2**	**Adsorption/desorption screening test** 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 [4]	**Other justification** [ ]	
Detailed justification:	This data end point is not applicable to carbon dioxide as a biocide as used by Rentokil Initial. In water, carbon dioxide breaks down to give carbonic acid, which is brought about by the result of simple dissolution of the carbon dioxide in water. $CO_2 + H_2O \leftrightarrow H_2CO_3$ It will attain equilibrium with air spaces in soil through passive diffusion. The carbon dioxide used here is not applied directly to the sediment and by calculation it can be shown that its use by Rentokil Initial will not cause any elevation in the levels of carbon dioxide in water, outside normal atmospheric ranges. *Refer to next page for full details of the scientific calculation, which supports this statement.* Continued……	

[redacted]

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

Detailed justification: (continued):	[redacted]
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

Table 4-2: Standard form for justification of the non-submission of data

Section 7.1.4 **Annex Point/TNsG** **Annex IIIA, XII. 2.2**	**Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *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:	This data end point is not applicable to carbon dioxide as a biocide as used by Rentokil Initial. In water, carbon dioxide breaks down to give carbonic acid, which is brought about by the result of simple dissolution of the carbon dioxide in water. $CO_2 + H_2O \leftrightarrow H_2CO_3$ It will attain equilibrium with air spaces in soil through passive diffusion. Under the normal conditions of use, the carbon dioxide used in Rentokil Initial's rodenticide (PT14) products will not be applied directly to the sediment, and by calculation it can be shown that its use by Rentokil Initial will not cause any elevation in the levels of carbon dioxide in water, outside normal atmospheric ranges. *Refer to next page for details of scientific calculation which supports this statement.* (Continued....)	

[redacted]

Section 7.1.4 Annex Point/TNsG Annex IIIA, XII. 2.2	**Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary** Section 7: Ecotoxicological Profile, including Fate and Behaviour

Detailed justification:

(Continued...)

[redacted]

Undertaking of intended data submission [ ]	Not applicable.

Section 7.1.4 **Annex Point/TNsG** **Annex IIIA, XII. 2.2**	**Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

Table 4-2: Standard form for justification of the non-submission of data

Section 7.1.4.1 **Annex Point/TNsG** **Annex IIIA, XII. 2.1**	**Field study on accumulation in the sediment** Section 7: Ecotoxicological Profile including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [✓]	**Other justification** [ ]	
Detailed justification:	This data end point is not applicable to carbon dioxide as a biocide as used by Rentokil Initial. Carbon dioxide will attain equilibrium with air spaces in soil through passive diffusion. Under normal conditions of use, the carbon dioxide used in Rentokil Initial's rodenticide (PT14) products will not be applied directly to the sediment, and by calculation it can be shown that its use by Rentokil Initial will not cause any elevation in the levels of carbon dioxide in water (outside normal atmospheric ranges) which in turn may run off into the sediment. *Refer to next page for details of scientific calculation which supports this statement.* (Continued...)	

[redacted]

Detailed justification:
(Continued...)

[redacted]

Undertaking of intended data submission [ ] Not applicable.

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

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

Table 4-2: Standard form for justification of the non-submission of data

Section 7.2.1 **Annex Point/TNsG** **Annex IIIA, VII.4, XII.1.1**	**Aerobic degradation in soil, initial study** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [✓]	**Other justification** [ ]	
Detailed justification:	Carbon dioxide, as a biocide, as used by Rentokil Initial is not applied or emitted directly to the soil and therefore this study is not required. Data requirements A7.1.1.2.1 and A7.1.1.2.2 do not indicate the need to conduct studies on the fate and behaviour of carbon dioxide in soil and in addition, this is substantiated by the fact that carbon dioxide does undergo a degree of abiotic degradation by means of simple dissolution in water. Also, it is well known that although carbon dioxide occurs predominantly in air, it will attain equilibrium with air spaces in soil through passive diffusion. 	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.2.1 Annex Point/TNsG Annex IIIA, VII.4, XII.1.1	**Aerobic degradation in soil, initial study** Section 7: Ecotoxicological Profile, including Fate and Behaviour

	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 A7.2.1
Annex Point IIIA, VII.4, XII.1.1

Aerobic degradation in soil, initial study

Official use only

1. REFERENCE

1.1	**Reference**	[redacted]
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2		
1.2.3	Criteria for data protection	[redacted]

2. GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No. Not carried out to OECD Guideline 106 and E.C test method C.18
2.2	**GLP**	No. No information available whether study complies with the requirements of GLP.
2.3	**Deviations**	Yes. No set guideline followed.

3. MATERIALS AND METHODS

3.1	**Test material**	As given in section 2.
3.1.1.	Lot/Batch number	Not reported.
3.1.2	Specification	[redacted]
		[redacted]
3.2	**Degradation products**	Not reported.
3.2.1	Method of analysis for degradation products	Not applicable.
3.3	**Reference substance**	No.
3.3.1	Method of analysis for reference substance	Reference substance not used.
3.4	**Soil types**	See table A7_2_1-1 at end of this study summary for details of study area.

3.5	**Testing procedure**	
3.5.1	Test system	Field observation of soil carbon dioxide concentration began in May 1993 at the Oak site (See table A7_2_1-1 at end of this study summary for details), and May 1995 at the Larch site (see table A7_2_1-1 at end of this study summary for details). The reported submitted gives details of results obtained by September 1999. The concentration of carbon dioxide in soil air was measured at depths of 0.1, 0.2, 0.3, 0.4, 0.5, 0.7, 1.0, 1.5, and 2.0 m below the ground surface.
3.5.2	Test solution and test conditions	Long term field observation of carbon dioxide in soil was conducted in a forested headwater basin. See table A7_2_1-1 at end of this study summary for details of study area.
3.6	**Test performance**	
3.6.1	Preliminary test	Not reported.
3.6.2	Screening test: Adsorption	Not reported.
3.6.3	Screening test: Desorption	Not reported.
3.6.4	HPLC method	Not reported.
3.6.5	Other test	Not reported.
		4 RESULTS
4.1	**Preliminary test**	
4.2	Screening test: Adsorption	Not reported.
4.3	Screening test: Desorption	Not reported.
4.4	Calculations	Based on results of repeated carbon dioxide measurement at the ground surface, a constant concentration value of 0.05% in volume is assumed. The soil carbon dioxide concentration generally increased with depth and was highest 1.0-1.5 m below the ground surface. Except for the area just below the ground surface carbon dioxide concentration in soil air was always >0.1%. At a depth of 2.0m , it usually exceeded 0.3%. The maximum concentration of 0.87% at the Oak site was measured at 1.0m on 27th August 1988. At the Larch site the maximum was 0.65% at 1.5 m on 3 September 1999. The carbon dioxide concentrations at the Oak site were generally higher than those at the Larch site.
4.4.1	Ka, Kd	Not reported.
4.4.2	Ka_{oc}, Kd_{oc}	Not reported.
4.5	Degradation Product(s)	Not included in the protocol.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and Methods

The concentration of carbon dioxide in soil air was measured at depths of 0.1, 0.2, 0.3, 0.4, 0.5, 0.7, 1.0, 1.5, and 2.0 m below the ground surface. The concentration of carbon dioxide in soil was determined with a Gastec gas detection device. A number of authors of previous studies have validated this method. At the beginning of the long-term observation, soil air collection probes were installed vertically to each depth with horizontal intervals of more than 0.3m. One probe was installed for each depth at each site. The probe consists of an 18 mm outer diameter PVC pipe with a 1.0 mm inner diameter tube inside, and is designed to enable the extraction of soil air from any depth without contamination or clogging. After pre-extraction of residual air from the collection probe, soil air was extracted from the probe and then introduced into the gas detection tube using a 100 ml hand pump. Carbon dioxide in the extracted air was immediately indicated by the length of the colour changed zone in the tube and recorded in the field. The concentration indicated by the gas detection tube was converted to % v/v carbon dioxide using a specific conversion calculation. Because the study area was located at elevations of more than 1500 m while the gas detection tube was calibrated for 1 atmosphere, atmospheric pressure correction was also needed.

Automatic data loggers at both sites continuously recorded atmospheric temperature and soil temperature at depths of 0.1, 0.3, 0.5, 0.7 and 1.0m. The pressure head of soil water was measured manually by tensiometers equipped with a mercury manometer at the depths of carbon dioxide measurements. Because the tensiometers froze, the pressure head could not be measured in winter. Daily precipitation was observed at Nobeyama, the Nagano Meterological Observatory Station nearest to the study area. Although a rain gauge is settled at the lower end of the experimental basin, it was inoperative from December to March. However, it has been confirmed that the amounts of rainfall observed at both rain gauges are similar during a snowless season.

Because the long-term field observation was conducted on a monthly basis, it is possible to show the typical seasonal patterns of carbon dioxide distribution in soil as a series of 12 carbon dioxide profiles, averaged monthly. A month was divided into three parts – the first 10 days, the middle 10 days and the last 8-10 days. The data was arithmetically averaged for each part of the month, and then a monthly average was calculated as the average of the three parts. In the absence of field observations for the first part of the month, the data obatined in the last part of the month was assigned. In the absence of field observations for the last part, the data from the first part of the next month was used. In the case of lack of data for the middle part of the month, the monthly mean was given by the average of the first and the last parts of the month. Several carbon dioxide profiles clearly different from the monthly trend were excluded from the calculation.

Using a similar procedure, monthly averaged data sets for soil temperature were compiled.

5.2	**Results and discussion**	
5.2.1	Adsorbed a.s [%]	Atmospheric temperatures observed at both sites were similar and mean annual temperature was 6.2°C for the observation period. The monthly mean temperature was highest in July or August (>15°C) and lowest in January or February (< -5°C). Annual temperature variations reached about 24°C, a characteristic feature of inland climate. The amount of precipitation is large in summer and small in winter. Soil temperatures at each depth were highest in August or September and lowest in February to April. Annual soil temperature variations ranged from 8-12°C at 1.0m deep to 16-18°C near the ground surface. Based on results of repeated carbon dioxide measurement at the ground surface, a constant concentration value of 0.05% in volume is assumed. The soil carbon dioxide concentration generally increased with depth and was highest 1.0-1.5 m below the ground surface. Except for the area just below the ground surface carbon dioxide concentration in soil air was always >0.1%. At a depth of 2.0m , it usually exceeded 0.3%. The maximum concentration of 0.87% at the Oak site was measured at 1.0m on 27th August 1988. At the Larch site the maximum was 0.65% at 1.5 m on 3 September 1999. The carbon dioxide concentrations at the Oak site were generally higher than those at the Larch site.
5.2.2	K_a	Not reported.
5.2.3	K_d	Not reported.
5.2.4	Ka_{oc}	Not reported.
5.2.5	Ka/Kd	Not reported.
5.2.6	Degradation products (% of a.s)	Not included in the protocol.
5.3	**Conclusion**	The soil carbon dioxide concentration generally increased with depth and was highest 1.0-1.5 m below the ground surface. Except for the area just below the ground surface carbon dioxide concentration in soil air was always >0.1%. At a depth of 2.0m , it usually exceeded 0.3%.
5.3.1	Reliability	3
5.3.2	Deficiencies	Rather than looking at aerobic degradation of carbon dioxide in soil, this study measured normal, background levels of carbon dioxide in a typical soil. It should be noted that the use of carbon dioxide by Rentokil Initial would increase the normal atmospheric concentrations of carbon dioxide in the locality.

Table A7_2_1-1: Description of study area

Location	Kawakami Experimental Basin. Mountainous headwater basin located at the east edge of Nagano Prefecture, central Japan.
Basin area	0.14 km^2 with elevations ranging from 1500 to 1690 m above sea level.
Atmospheric temperature	6.2°C (lower end of basin)
Annual precipitation	1450 mm (producing 830 mm of runoff)
Soil depth and description	Brown forest soil, 1.6m in depth. Neocene Meshimori-yama volcanic rocks underlie the soil mantle. A small ridge separates the basin into two smaller sub-basins, the North and South Valley.
Vegetation	Two types: a natural broadleaf forest composed mainly of oak (*Quercus mongolica* Fisch) and a Japanese larch (*Larix leptolepis* Gordon) plantation. Both forest floors are densely covered with bamboo grass (*Sasa nipponica)*. Two field observation sites, the Oak site and the Larch site were established to study soil carbon dioxide concentrations for both vegetation sites.
Description of observation site: Oak site	Sited in North valley, at an altitude of 1500m on the lower part of a steep southwest facing slope (average gradient 25°). Stand density is 9.4 trees per 100 m^2 average diameter at breast height (DBH) is 19.7 cm and tree height averages 13-16m. The average tree age is roughly 60 years. The soil at the Oak site has developed to a depth of nearly 6 m due to an accumulation of colluvium from the upper part of the slope. The A layer of the soil profile is 0.2-0.3 m thick, with the B layer following just under it, thin layers of angular gravel are found at several depths. The organic layer on the ground surface is not continuous.
Description of observation site: Larch site	Sited at the lower end of the basin, at an altitude of 1510 m on a relatively gentle north-facing slope (average gradient 15°). The Japanese Larch was planted in 1964-1965. The averages of stand density, diameter at breast height (DBH) and tree height are 8.1 trees per 100 m^2, 21.3 cm and about 19 m respectively. Litter fall from Japanese larches thickly covers the forest floor. The A layer of the soil profile is 0.2-0.5m thick. Clods of weathered material are found below 1.5m, but no gravel layer is found in the profile.

Section A7.2.1 **Aerobic degradation in soil, initial study**
Annex Point IIIA, VII.4, XII.1.1

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and Methods	*State if 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	Other conclusions: *(adopt applicant's version or include revised version)*
Reliability	*Based on 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 if 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 4-2: Standard form for justification of the non-submission of data

Section 7.2.2 **Annex Point/TNsG** **Annex IIIA, XII.1.1**	**Aerobic degradation in soil, further studies** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [✓]	**Technically not feasible** [ ] **Scientifically unjustified** [✓] **Other justification** [ ]	
Detailed justification:	Carbon dioxide, as a biocide, as used by Rentokil Initial is not applied or emitted directly to the soil and therefore this study is not required. Data requirements A7.1.1.2.1 and A7.1.1.2.2 do not indicate the need to conduct studies on the fate and behaviour of carbon dioxide in soil and in addition, this is substantiated by the fact that carbon dioxide does undergo a degree of abiotic degradation by means of simple dissolution in water. Also, it is well known that although carbon dioxide occurs predominantly in air, it will attain equilibrium with air spaces in soil through passive diffusion.	
Undertaking of intended data submission [ ]	Not applicable.	

[redacted]

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

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

Table 4-2: Standard form for justification of the non-submission of data

Section 7.2.2.1 **Annex Point/TNsG** **Annex IIIA, VII.4, XII.1.1, XII.1.4**	**The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [✓]	**Technically not feasible** [ ] **Scientifically unjustified** [✓] **Other justification** [ ]	
Detailed justification:	Carbon dioxide, as a biocide, as used by Rentokil Initial is not applied or emitted directly to the soil and therefore this study is not required. Data requirements A7.1.1.2.1 and A7.1.1.2.2 do not indicate the need to conduct studies on the fate and behaviour of carbon dioxide in soil and in addition, this is substantiated by the fact that carbon dioxide does undergo a degree of abiotic degradation by means of simple dissolution in water. Also, it is well known that although carbon dioxide occurs predominantly in air, it will attain equilibrium with air spaces in soil through passive diffusion.	
Undertaking of intended data submission [ ]	Not applicable.	

[redacted]

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

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