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

Section 6.12.6 **Annex Point IIA, VI, 6.9.6**	**Sensitisation/allergenicity observations, if available.**	
	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 [4]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	There is no data about the sensitisation or allergenicity of workers and other persons exposed to carbon dioxide, and there is no data with regards to hypersensitivity available for submission. In addition, a full literature search was conducted in order to identify and obtain any sensitisation, allergenicity or hypersensitivity data on carbon dioxide that is available in the public domain. No relevant data was found from this search. Note that the "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that data about the sensitisation, allergenicity or hypersensitivity effects of carbon dioxide in exposed persons should only be submitted if it is available.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 6.12.6	Sensitisation/allergenicity observations, if available.

	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 A6.12.7
Annex Point IIA, VI, 6.9.7

Specific treatment in case of poisoning: first aid measures, antidotes and medical treatment, if known

Already submitted for carbon dioxide dossier for Product Type 14.

[redacted]

1. **REFERENCE**

Official use only

1.1 Reference

[redacted]

1.2 Details

Inhalation:	Cylinder: This route of exposure is not anticipated. Fumigation bubble: Remove patient to fresh air, keep warm and at rest. Apply supportive measures if necessary and seek medical attention.
Eye contact:	Cylinder: This route of exposure is not anticipated. Fumigation bubble: Rinse affected eye with clean running water, or eyewash solution, for at least 15 minutes holding eyelids well apart. Rinse entire surface and do not allow run-off to contaminate unaffected eye. Seek medical attention.
Skin contact:	Cylinder: This route of exposure is not anticipated. Fumigation bubble: Remove and wash contaminated clothing immediately. Wash affected area thoroughly with soap and water. If the patient feels unwell seek medical advice.
Ingestion:	Cylinder and fumigation bubble: This route of exposure is not anticipated

Section A6.12.8
Annex Point IIA, VI, 6.9.8

Prognosis following poisoning

Already submitted for carbon dioxide dossier for Product Type 14.
[redacted]

1. **REFERENCE**

Official use only

1.1 References

[redacted]

1.2 Details

Symptoms of excessive exposure by inhalation include headache, dizziness, shortness of breath, muscular weakness, drowsiness and ringing in the ears. At high concentrations carbon dioxide may cause asphyxiation and can paralyse the respiratory centre. Breathing an atmosphere rich in carbon dioxide can cause immediate loss of consciousness and death may occur. Symptoms of asphyxiation may include rapid and gasping respiration, rapid fatigue, nausea, vomiting, cyanosis and may lead to loss of consciousness or death from anoxia.

The effects of excessive carbon dioxide exposure are reversible within a few minutes / hours of carbon dioxide withdrawal.

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

Section 6.13 **Annex Point IIA, VI, 2**	**Toxic Effects on Livestock and Pets**	
	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:	It is not scientifically necessary to submit tests considering the toxic effects of carbon dioxide in livestock and pets 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 in areas where animals are housed, kept or transported, or exposure is via drinking water or feeding stuffs. Carbon dioxide as an insecticide fumigant would not be used in such areas. It is therefore not scientifically necessary to carry out any further investigations about the toxicity of carbon dioxide to livestock and pets, other than that reported under section 6.1.3 Acute Toxicity: Inhalation. (continued……)	
Undertaking of intended data submission [ ]	Not applicable.	

Section 6.13 Annex Point IIA, VI, 2	Toxic Effects on Livestock and Pets

	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 6.14 **Annex Point IIIA, XI, 2**	**Other Test(s) Relating to the Exposure of Humans** Already submitted for carbon dioxide dossier for Product Type 14.	
	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:	It is not scientifically necessary to submit tests considering the toxicity of degradation products, by-products and reaction products relating to human exposure of carbon dioxide because the "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market : Guidance on Data Requirements for Active Substances and Biocidal Products" states that these tests are only required if the active ingredient generates substances, other than mammalian metabolites, in it's normal use. Carbon dioxide is a ready-to-use insecticide product so it is not added to any other chemicals during it's normal use. The physical chemical profile of carbon dioxide suggests that it is not reactive, so is unlikely generate any harmful substances during it's normal use. It is on this basis that no additional tests have been submitted which consider the toxicity of degradation products, by-products and reaction products relating to human exposure to carbon dioxide.	
Undertaking of intended data submission [ ]	Not applicable.	

Section 6.14 Annex Point IIIA, XI, 2	Other Test(s) Relating to the Exposure of Humans

	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 6.15 **Annex Point IIIA, VI, 4**	**Food and Feedingstuffs**	
	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** [4]	
Detailed justification:	Carbon dioxide as a biocide, may be used on certain foodstuffs infested with invertebrate pests. It is not necessary however to submit tests relating to its toxicity in food and feeding stuffs for the following reasons: 1. Once the fumigation process has been completed and all the carbon dioxide vented away to atmosphere, there will be no carbon dioxide residues remaining. Measuring and detection devices are used to monitor carbon dioxide levels present during and after a fumigation has occurred. 2. Due to the fact that no carbon dioxide residues are left on ingredients, finished food products or on equipment[1], carbon dioxide was granted exemption from food residue tolerance by the US Environmental Protection Agency (EPA) in 1980 when used on all raw agricultural commodities[2]. 3. Carbon dioxide is classified as a Permitted Miscellaneous Additive in Foods (Serial no, E290) without stated limits other than those consistent with responsible manufacturing procedures[3]. As such, the following data end points do not have to be met: 6.15.1 Identification of the residues (identity and concentrations), degradation and reaction products and of metabolites of the active substance in contaminated foods or feeding stuffs. 6.15.2 Behaviour of the residues of the active substance, its degradation and reaction products and, where relevant, its metabolites on the treated or contaminated food or feeding stuffs including the kinetics of disappearance. 6.15.3 Estimation of potential or actual exposure of the active substance to humans or animals through food and feeding stuffs and other means. 6.15.4 Proposed acceptable residues and the justification of their acceptability. 6.15.5 Any other available information which is relevant. 6.15.6 Summary and evaluation of data submitted under point 6.15 (continued...)	

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 6.16 **Annex Point IIIA, VI, 3.5 and XI, 2**	**Any Other Tests Related to the Exposure of the Active Ingredient to Humans, in it's Proposed Biocidal Products**	
	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** [4]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [ ]	
Detailed justification:	It is not necessary to submit any additional tests related to the exposure of carbon dioxide to humans in it's proposed biocidal products (other than what has already been submitted elsewhere) given the use pattern and toxicity profile of carbon dioxide. The normal working practices of carbon dioxide as an insecticide fumigant are within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected. Carbon dioxide levels are monitored in the immediate vicinity of a fumigation bubble and should levels reach 0.5%, an alarm will sound automatically. (Continued….)	
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 6.17 **Annex Point IIIA, VI, 6**	**Toxic Effect of Metabolites from Treated Plants** Already submitted for carbon dioxide dossier for Product Type 14.	
	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** [4]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **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	

Please note that the following information is taken from Document IIA (Section 3).

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. Due to the engineering controls in place, the normal use of carbon dioxide as an insecticide fumigant does not result in the exposure of operators or bystanders (of which there should be none) to elevated levels. 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).	Document III-A6 Section 6.2

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.	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. Due to the engineering controls in place, the normal use of carbon dioxide as an insecticide fumigant does not result in the exposure of operators or bystanders (of which there should be none) to elevated levels.	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.	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.	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 workplace exposure limit for carbon dioxide set in the UK is 5,000 ppm / 0.5% (8 hour time weighted average) while the short term workplace 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 long-term workplace exposure limit of 0.5% has been used in the risk assessment. This is because: Due to the engineering controls in place, the normal use of carbon dioxide as an insecticide fumigant does not result in the exposure of operators or bystanders (of which there should be none) to elevated levels. In addition, carbon dioxide levels are monitored in the immediate vicinity of a fumigation bubble and should levels reach 0.5% an alarm will sound. 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. In addition, due to the engineering controls in place, the normal use of carbon dioxide as an insecticide fumigant does not result in the exposure of operators or bystanders (of which there should be none) to elevated levels. 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)	Document III-A6 Section 6.6.1 Document III-A6 Section 6.6.2 Document III-A6 Section 6.6.3

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.	On the basis of exposure alone, it is not scientifically necessary to conduct an *in vivo* mammalian bone marrow cytogenetic test or micronucleus test for carbon dioxide. As under normal working practices, the use of carbon dioxide as an insecticide fumigant is within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected. In addition, there is no existing data available which suggests that carbon dioxide is a genotoxic compound.	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. The normal working practices of carbon dioxide as an insecticide fumigant are within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected. 2. In addition to the above, the potential for exposure to carbon dioxide is minimal as it is manufactured [redacted] This means there is no exposure to workers, bystanders or the environment, during manufacture. 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. 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 caused 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, can be used to support the teratogenic assessment of CO_2 because:

1. The normal working practices of carbon dioxide as an insecticide fumigant are within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected.
2. In addition to the above, the potential for exposure to carbon dioxide is minimal as it is manufactured in a completely enclosed system. This means there is no exposure to workers, bystanders or the environment, during manufacture.
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 testis 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 weights of accessory glands were 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. Whilst 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, can be used to support the teratogenic assessment of CO_2 because:

1. The normal working practices of carbon dioxide as an insecticide fumigant are within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected.
2. In addition to the above, the potential for exposure to carbon dioxide is minimal as it is manufactured [redacted] This means there is no exposure to workers, bystanders or the environment, during manufacture.
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 5^{th}, 6^{th} and 8^{th} to 11^{th} 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. Whilst 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, can be used to support the teratogenic assessment of CO_2 because:

1. The normal working practices of carbon dioxide as an insecticide fumigant are within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected.
2. In addition to the above, the potential for exposure to carbon dioxide is minimal as it is manufactured [redacted] This means there is no exposure to workers, bystanders or the environment, during manufacture.
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. The normal working practices of carbon dioxide as an insecticide fumigant are within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected.

2. In addition to the above, the potential for exposure to carbon dioxide is minimal as it is manufactured [redacted] This means there is no exposure to workers, bystanders or the environment, during manufacture.

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. 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 were 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.

The normal working practices of carbon dioxide as an insecticide fumigant are within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected.

In addition to the above, the potential for exposure to carbon dioxide is minimal as it is manufactured [redacted] This means there is no exposure to workers, bystanders or the environment, during manufacture.

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. It is not necessary to submit data to consider the toxicity of carbon dioxide in food or feeding stuffs because although carbon dioxide is used on certain foodstuffs: 1. Once the fumigation process has been completed and all the carbon dioxide vented away to atmosphere, there will be no carbon dioxide residues remaining. Measuring and detection devices are used to monitor carbon dioxide levels present during and after a fumigation has occurred. 2. Due to the fact that no carbon dioxide residues are left on ingredients, finished food products or on equipment, carbon dioxide was granted exemption from food residue tolerance by the US Environmental Protection Agency (EPA) in 1980 when used on all raw agricultural commodities. 3. Carbon dioxide is classified as a Permitted Miscellaneous Additive in Foods (Serial no, E290) without stated limits other than those consistent with responsible manufacturing procedures. Carbon dioxide is also not intended for use directly on plants, making it unnecessary to consider the toxic effect of metabolites from treated plants. The normal working practices of carbon dioxide as an insecticide fumigant are within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected. In addition to the above, the potential for exposure to carbon dioxide is minimal as it is manufactured in [redacted] This means there is no exposure to workers, bystanders or the environment, during manufacture.	Document III-A6 Section 6.10 Document III-A6 Section 6.11 Document III-A6 Section 6.14 Document III-A6 Section 6.15 Document III-A6 Section 6.16 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 Already submitted for carbon dioxide dossier for Product Type 14.	
	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

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 Already submitted for carbon dioxide dossier for Product Type 14.
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]

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	

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Role, Fate and Behaviour of Carbon Dioxide in the Environment

1. Introduction

Carbon dioxide occurs naturally in the atmosphere. The normal atmospheric concentration of carbon dioxide is approximately 0.03 % v/v, but this can vary slightly depending on atmospheric conditions such as temperature, humidity and air quality (levels of pollution).

Carbon dioxide plays several vital roles in the environment. These include:

1. Carbon dioxide is one of a number of greenhouse gases present in the atmosphere. Without the presence of greenhouse gases, heat from the sun would return to space in the form of infra-red radiation. Carbon dioxide, and the other greenhouse gases absorb some of this radiation and prevent it's release, thereby warming the earth sufficiently to support life.*
   *Too much carbon dioxide in the atmosphere, e.g. as a result of burning fossil fuels, places the earth at risk from an increase of this effect, otherwise known as "global warming".

2. Carbon dioxide is an essential carbon source used by plants to produce carbohydrate for growth, through the process of photosynthesis.
   Carbon dioxide + water + sunlight ⟨ carbohydrate + oxygen

3. Carbon dioxide plays a crucial role in the chemical weathering of rocks. Through weathering, outcrops of sedimentary, metamorphic, and igneous rocks are broken down to form sediments and soils. The resulting soils are essential for supporting the terrestrial food chain. Wind and water erosion may redistribute sediments on continents or deposit them into nearby oceans and seas.

This report summarises the current knowledge about the fate and behaviour of carbon dioxide in the environment, and its essential role in supporting life on earth.

2. Fate and Behaviour of Carbon Dioxide in the Environment: The carbon cycle

All life is based on the element, carbon. Carbon is stored on Earth in the following ways (these are called major sinks of carbon):

1. Stored as organic molecules in living and dead organisms found in the biosphere[a].
2. Stored as the gas carbon dioxide in the atmosphere[b].
3. Stored as organic matter in soils.
4. Stored in the lithosphere[c] as fossil fuels or rock deposits such as limestone and chalk.
5. Stored in the oceans as dissolved atmospheric carbon dioxide or calcium carbonate shells in marine organisms.

Definitions:
a. Biosphere is that part of the earth and atmosphere capable of supporting living organisms.
b. The atmosphere is defined as the envelope of air surrounding the Earth.
c. Lithosphere is the layer of solid, brittle rock making up the outer 100 kilometers of the Earth, encompassing both the crust and the outermost part of the upper mantle.

The table below shows the estimated major stores of carbon on the Earth.

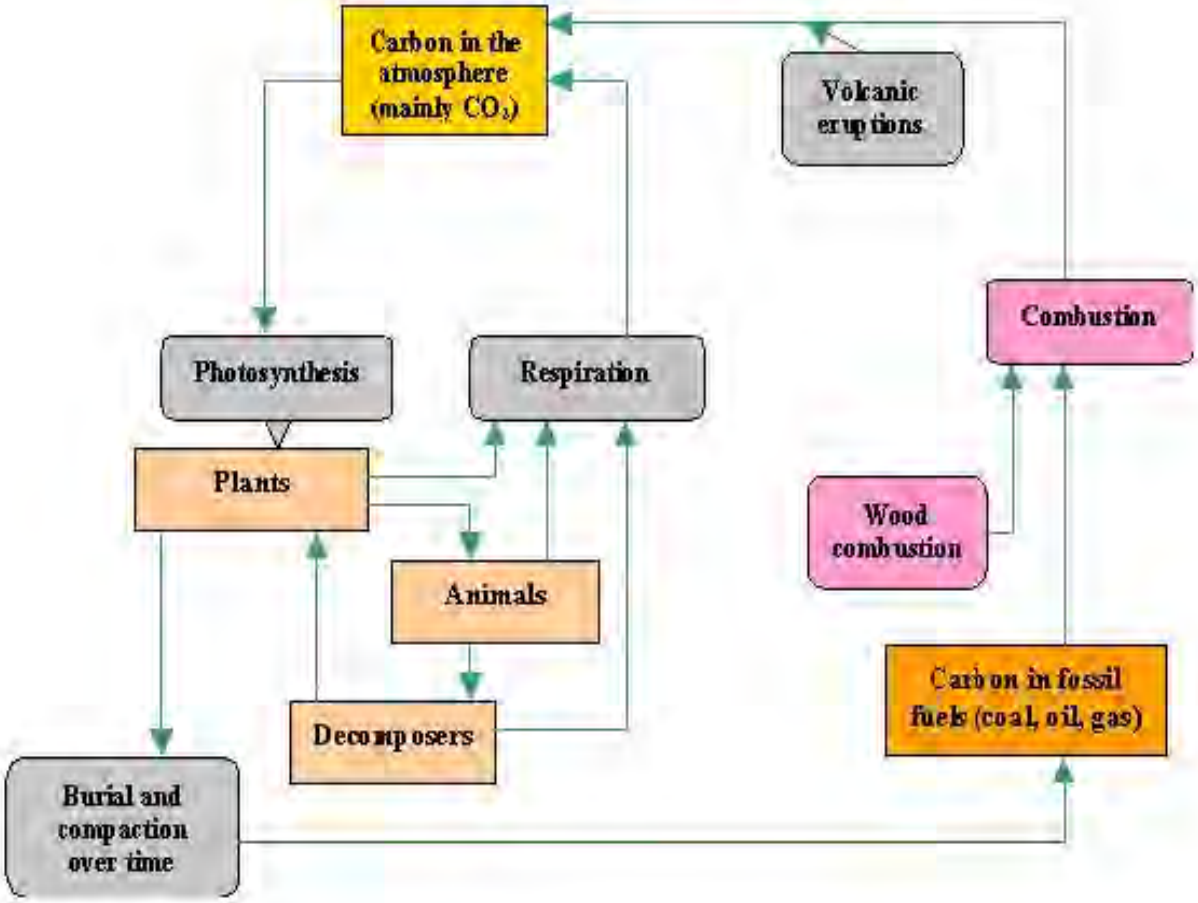
Table 1: Estimated major stores of carbon on the Earth.
Figure from: www.physicalgeography.net/fundamentals/9r.html

Sink	Amount in Billions of Metric Tons
Atmosphere	578 (as of 1700) - 766 (as of 1999)
Soil Organic Matter	1500 to 1600
Ocean	38,000 to 40,000
Marine Sediments and Sedimentary Rocks	66,000,000 to 100,000,000
Terrestrial Plants	540 to 610
Fossil Fuel Deposits	4000

The movement of carbon is well established and is modelled by the "Carbon Cycle". The carbon cycle is based on carbon dioxide, and naturally consists of two parts- the aquatic carbon cycle which is concerned with the movement of carbon through aquatic ecosystems, and the terrestrial carbon cycle which models the movement of carbon through terrestrial ecosystems.

The terrestrial carbon cycle.

Figure 1: Movement of carbon in the terrestrial ecosystem
(figure from http://www.learntech.com/carbon-cycle.htm)



As shown in figure 1, terrestrial ecosystems rely on carbon dioxide from the atmosphere. Terrestrial plants, and other autotrophic organisms, absorb carbon dioxide into their cells and via the process of photosynthesis, chemically convert it to carbon-based sugar molecules and oxygen. Both of these products of photosynthesis sustain animal life.

The carbon-based sugar molecules produced by photosynthesis can be chemically modified by the organism that produced them. The sugar molecules can be modified by the metabolic addition of other elements to produce more complex compounds like proteins, cellulose and amino acids. These compounds are either used by the plant as their energy source to carry out their life functions, or stored as excess biomass. Consumers, such as animals, fungi and bacteria, get their energy through the consumption of this excess biomass. This consumption can occur when the plant is alive or dead (i.e. decomposition).

The energy within carbon-based sugar molecules (biomass) is released via the process of cellular respiration. Aerobic animals and micro-organisms use the oxygen produced as a by-product of photosynthesis to release this energy, summarised in the following equation:

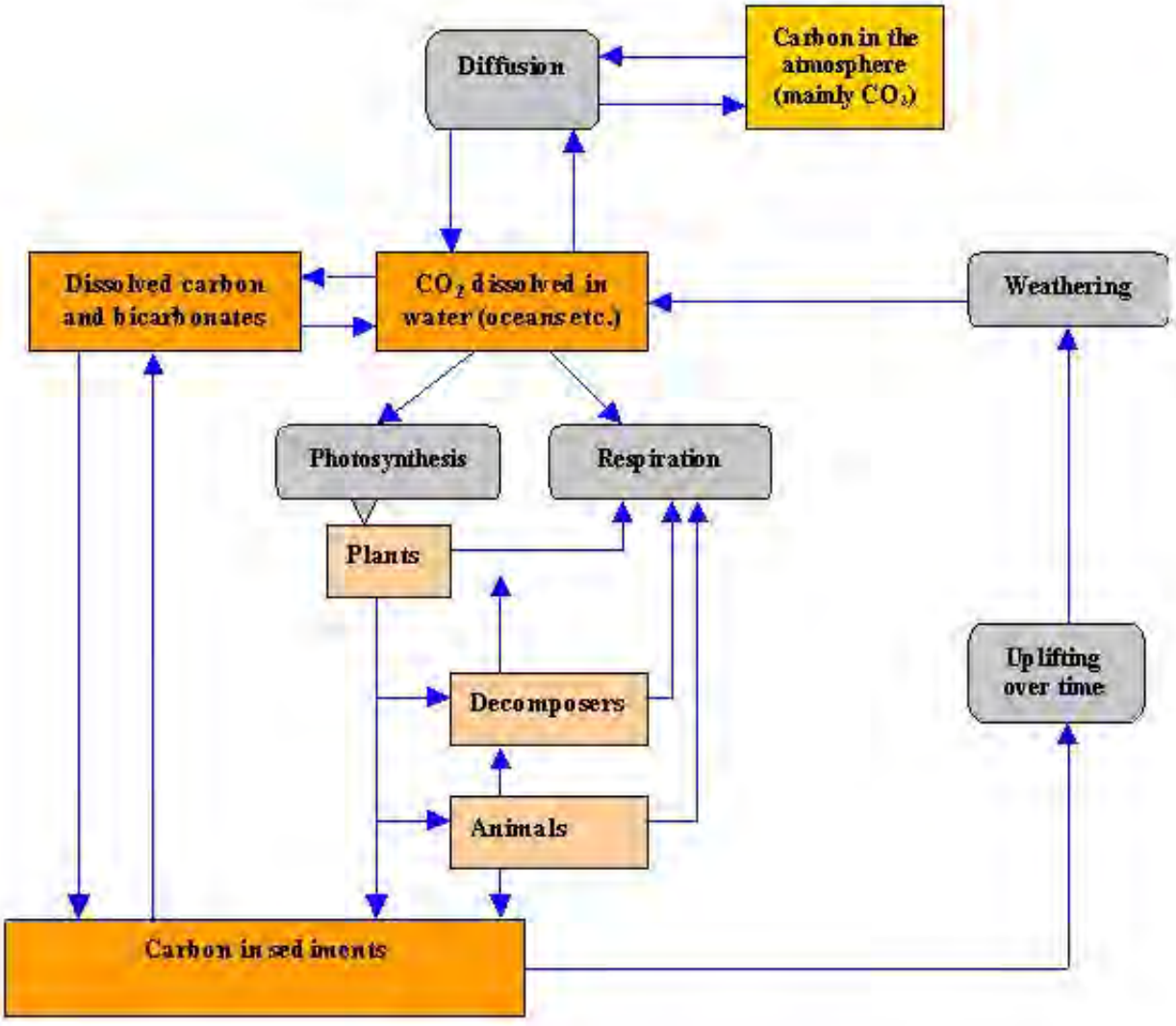
$C_6H_{12}O_6 + 6O_2 \rightarrow 6CO_2 + 6H_2O + \text{energy}$
(glucose)

The carbon dioxide produced in the process of cellar respiration is released back into the atmosphere for reuse by photosynthetic plants, and other autotrophic organisms.

Table 1 shows stores of carbon (called sinks). These exist because not all organic matter is immediately decomposed to release carbon dioxide back into the atmosphere for re-use by photosynthetic plants, and other autotrophic organisms. Under certain conditions, dead plant and animal matter accumulates faster than it is decomposed within an ecosystem. The remains of dead plant and animal matter can accumulate in under ground deposits. When layers of sediment compress this matter, fossil fuels will eventually be formed (after many centuries). Long-term geological processes will eventually release the carbon in fossil fuel back in to the air (as carbon dioxide), but normally this carbon is released during combustion by humans (as carbon dioxide). Addition of carbon dioxide to air may also occur during volcanic eruptions.

The aquatic carbon cycle.

Figure 2: Movement of carbon in the aquatic ecosystem
(figure from http://www.lenntech.com/carbon-cycle.htm)



As shown in figure 2, carbon dioxide, from the atmosphere, enters the waters of the ocean by simple diffusion. Once dissolved in seawater, it is available to photosynthetic aquatic plants, and other autotrophic organisms who chemically convert it to carbon-based sugar molecules and oxygen (as described above under "the terrestrial carbon cycle").

Some of the carbon dioxide, when dissolved in seawater will remain as it is, or it forms weak carbonic acid. Carbonic acid dissociates into hydrogen ions, carbonate (CO_3^{-2}) or bicarbonate (HCO_3^-) ions. Certain forms of sea life biologically fix bicarbonate with calcium (Ca^{+2}) to produce calcium carbonate ($CaCO_3$). Calcium carbonate is used produce shells and other body parts by organisms such as coral, clams, oysters, some protozoa, and some algae. When these organisms die, their shells and body parts sink to the ocean floor where they accumulate as carbonate-rich deposits. After long periods of time, these deposits are physically and chemically altered into sedimentary rocks.

Carbon dioxide plays a crucial role in the chemical weathering of rocks. Through weathering, outcrops of sedimentary, metamorphic, and igneous rocks are broken down to form sediments and soils. The resulting soils are essential for supporting the terrestrial food chain. As described above, carbon dioxide, when dissolved in water may form weak carbonic acid, the carbonic acid dissociates into hydrogen ions and bicarbonate ions. The hydrogen ions and water react with silicates and carbonates present in rock, altering the surface of the rock. The products of weathering are predominately clays (a group of silicate minerals), and soluble ions such as calcium, iron, sodium and potassium. Carbon dioxide is released back into the atmosphere through the process of weathering, where it is available for re-use either in the aquatic carbon cycle, or the terrestrial carbon cycle.

3. Carbon dioxide: The role of the carbon cycle as a natural buffer to maintain atmospheric concentrations within acceptable limits

Carbon dioxide, because it is a greenhouse gas, plays an important role in maintaining the Earth's climate. Without the presence of greenhouse gases, heat from the sun would return to space in the form of infra-red radiation. Carbon dioxide, and the other greenhouse gases absorb some of this radiation and prevent it's release, thereby warming the earth sufficiently to support life.* Feedbacks in the carbon cycle act to maintain carbon dioxide levels within certain limits, so that the climate does not get too hot or too cold to support life**. The carbon cycle is a large-scale example of LeChatelier's principle. LeChatelier's principle states that if a chemical reaction is at equilibrium and it is disturbed by the addition or removal of a product or reactant, the reaction will adjust so as to attempt to bring that chemical species back to it's original concentration. Some examples of how the carbon cycle adjusts to maintain carbon dioxide levels within certain limits are given below.

1. Some of the carbon dioxide, when dissolved in seawater will remain as it is, or it forms weak carbonic acid. Carbonic acid dissociates into hydrogen ions, carbonate (CO_3^{-2}) or bicarbonate (HCO_3^-) ions. As carbonic acid is removed from the aquatic environment by weathering of rocks, the reaction will adjust by producing more carbonic acid Since the dissolved carbon dioxide in water is in equilibrium with atmospheric carbon dioxide, more carbon dioxide is removed from the atmosphere to replace that removed from solution by weathering.

2. If carbon dioxide increases in the atmosphere because of a volcanic eruption, global temperature will rise. Rising temperature and more dissolved carbon dioxide will lead to increased weathering of crustal rocks as a result of faster reaction rates (temperature effect) and greater acidity. Enhanced weathering will use up the excess carbon dioxide thereby cooling the climate.

3. Conversely to the situation described in (2), if the global temperature cools as a result of some astronomical event, the lower temperatures will result in lower rates of chemical weathering. Decreased weathering means less carbon dioxide being drawn from the atmosphere by weathering reactions, leaving more carbon dioxide in the atmosphere to increase temperatures.

4. If more rocks become available for rapid weathering as a result of mountain uplift the enhanced weathering will draw down atmospheric carbon dioxide and decrease global temperatures. But the decreased temperatures will slow reaction rates, thereby using less carbon dioxide, thus allowing temperatures to moderate.

*Too much carbon dioxide in the atmosphere, e.g. as a result of burning fossil fuels, places the earth at risk from an increase of this effect, otherwise known as "global warming".

**The effects described will only work to a point. If humans add significant volumes of carbon dioxide into the atmosphere e.g. through burning of fossil fuels and remove or modify natural sinks for the carbon dioxide like plant cover in forests and grassland, carbon dioxide levels in the atmosphere will rise leading to warming of the earth's climate.

4. Conclusion

This report demonstrates that carbon dioxide plays an essential role in supporting life on earth. Carbon dioxide is continuously moves through different environmental compartments, through natural processes. Feedbacks in the equilibrium reactions present between environmental compartments, mean that carbon dioxide concentrations in both aquatic and terrestrial ecosystems remain stable.

References

1. Anon (2005) The Carbon Cycle. From: www.physicalgeography.net/fundamentals/9r.html Applicant's reference CO2 268

2. Anon (2005) Carbon Cycle From: www.lenntech.com/carbon-cycle.htm Applicant's reference CO2 269

3. Anon (2005) Cellular Respiration From: http://en.wikipedia.org/wiki/Cellular_respiration Applicant's reference CO2 270

4. Anon (2005) Weathering From: http://regentsprep.org/Regents/earthsci/units/weathering/weathering.cfm Applicant's reference CO2 271

5. Anon (2005) The Carbon Cycle and Earth's Climate From: www.columbia.edu/~vjd1/carbon.htm Applicant's reference CO2 272

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 Already submitted for carbon dioxide dossier for Product Type 14.	
	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 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

	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 Already submitted for carbon dioxide dossier for Product Type 14.	
	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

Already submitted for carbon dioxide dossier for Product Type 14. Amendments made to the section on deficiencies.

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 [redacted]

3.1.1. Lot/Batch number [redacted]

3.1.2 Specification [redacted]

3.2 Reference substance No.

3.2.1 Initial concentration of reference substance Not used.

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

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. Effects of soil organic matter (elevational gradient) on partial pressure of carbon dioxide in streams: Great Smoky Mountains National Park survey 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 ($p < 0.001$). Effects of drainage basin area and stream size on partial pressure of carbon dioxide in streams (longitudinal trends). 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...

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

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....

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. <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.
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 supersaturated 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 increasing 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. The normal working practices of carbon dioxide as an insecticide fumigant are within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected.

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 Already submitted for carbon dioxide dossier for Product Type 14.	
	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 Already submitted for carbon dioxide dossier for Product Type 14.	
	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]

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 Already submitted for carbon dioxide dossier for Product Type 14.

	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 Already submitted for carbon dioxide dossier for Product Type 14.	
	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:	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 Already submitted for carbon dioxide dossier for Product Type 14.	
	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:	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]

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 Already submitted for carbon dioxide dossier for Product Type 14.

	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 in biodegradable 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 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 Already submitted for carbon dioxide dossier for Product Type 14.	
	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:	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 Already submitted for carbon dioxide dossier for Product Type 14.	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [✓]	**Technically not feasible** [✓] **Scientifically unjustified** [✓] **Other justification** [ ]	
Detailed justification:	The 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 insecticide (PT18) 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]