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

Section 7.4.2 **Annex Point/TNsG** **Annex IIA, VII.7.5**	**Bioconcentration** 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** [**4**] **Other justification** [ ]	
Detailed justification:	"Bioconcentration" is the process leading to a higher concentration of, for example, a pesticide in an organism than in environmental media to which it is exposed. Since CO_2 is a naturally occurring substance that all living organisms are exposed to, and which plays a vital role in the normal maintenance of life, studies into the bioconcentration are not justified. The partition coefficient of CO_2 is 2.26 (isobutanol/water) and 1.74 (olive oil/water). The n-octanol/water partition coefficient has been calculated to be 0.83. The report submitted under the data end point "7.1.1.1. Hydrolysis as a function of pH and identification of breakdown products" characterises the role, fate and behaviour of carbon dioxide in the environment.	
Undertaking of intended data submission [ ]	Not applicable	

Section 7.4.2 Annex Point/TNsG Annex IIA, VII.7.5	**Bioconcentration** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

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

Section 7.4.3 **Annex Point/TNsG** **Annex IIIA, XIII.2**	**Effects on Aquatic Organisms, further studies** Section 7: Ecotoxicological Profile, including Fate and Behaviour Already submitted for carbon dioxide dossier for Product Type 14. Amendments made to the sections on specification and deficiencies.	
	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:	Effects on aquatic organisms is not required as carbon dioxide is not intended to be either used or released into aquatic environments. For these purposes, it is intended that CO_2 be used as a biocide in a closed system. These studies are only required if the results of 7.4.1.1, 7.4.1.2, 7.4.1.3 and 7.4.1.4 indicate a danger to the environment, as this is not indicated further tests are not required. [redacted]	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3 Annex Point/TNsG Annex IIIA, XIII.2	**Effects on Aquatic Organisms, further studies** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

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

Section 7.4.3.1 **Annex Point/TNsG** **Annex IIIA, XIII.2.1**	**Prolonged toxicity to an appropriate species of fish.** Section 7: Ecotoxicological Profile, including Fate and Behaviour 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:	This test is not usually required. Results of 7.4.1.1, 7.4.1.2, 7.4.1.3 and 7.4.1.4 do not indicate further testing is required. Carbon dioxide is not intended to be either used or released into aquatic environments. For these purposes, it is intended that CO_2 be used as a biocide in a closed system. [redacted]	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.1 Annex Point/TNsG Annex IIIA, XIII.2.1	**Prolonged toxicity to an appropriate species of fish.** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

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

Section 7.4.3.2 **Annex Point/TNsG** **Annex IIIA, XIII.2.2**	**Effects on reproduction and growth rate of fish.** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	These data are only required if the data given in the core base set indicates a need for further testing. A requirement for further testing is not indicated. Study summaries are given in the core base data set for two pieces of work investigating the effects of carbon dioxide to fish. One of which shows that dissolved concentrations of up to 6.3% carbon dioxide have not given rise to irreversible physiological and behavioural effects. [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 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 7.4.3.3.1 **Annex Point/TNsG** **Annex IIIA, XIII.2.3**	**Bio-accumulation in an appropriate species of fish.** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✔]	
Detailed justification:	This information is only required when there is a risk of secondary poisoning or there are other features indicating bio-accumulation. There is no risk of secondary poisoning of fish with the use of carbon dioxide. Carbon dioxide is a naturally occurring substance that all living organisms are exposed to, and which plays a vital role in the normal maintenance of life. Carbon dioxide in this case is used in a closed system, it is later released to the atmosphere. [redacted]	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.3.1 Annex Point/TNsG Annex IIIA, XIII.2.3	**Bio-accumulation in an appropriate species of fish.** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

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

Section 7.4.3.3.2 **Annex Point/TNsG** **Annex IIIA, XIII.2.4**	**Bio-accumulation in an appropriate invertebrate species.** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✔]	
Detailed justification:	This information is only required when there is a risk of secondary poisoning or there are other features indicating bio-accumulation. There is no risk of secondary poisoning with the use of carbon dioxide. Carbon dioxide is a naturally occurring substance that all living organisms are exposed to, and which plays a vital role in the normal maintenance of life. Carbon dioxide in this case is used in a closed system, it is later released to the atmosphere and is not available to the aquatic environment. [redacted]	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.3.2 Annex Point/TNsG Annex IIIA, XIII.2.4	**Bio-accumulation in an appropriate invertebrate species.** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

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

Section 7.4.3.4 **Annex Point/TNsG** **Annex IIIA, XIII.2.4**	**Effects on reproduction and growth rate with an appropriate invertebrate species.** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	This information is only required when chronic exposure is expected, or there are other features indicating the need for this test. There will be no chronic exposure as described in the core base data set the carbon dioxide is a naturally occurring substance that all living organisms are exposed to, and which plays a vital role in the normal maintenance of life. Carbon dioxide in this case is used in a closed system, it is later released to the atmosphere and is not available to the aquatic environment. 	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.4 Annex Point/TNsG Annex IIIA, XIII.2.4	**Effects on reproduction and growth rate with an appropriate invertebrate species.** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

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

Section 7.4.3.5 **Annex Point/TNsG** **Annex IIIA, XIII.3.4**	**Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk.** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	This information is only required if the data from other ecotoxicity tests indicates the need to do so, or if there is a need indicated by the intended use. Other ecotoxicity tests on carbon dioxide do not indicate that further testing is required. [redacted]	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.5 Annex Point/TNsG Annex IIIA, XIII.3.4	**Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk.** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

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

Section 7.4.3.5.1 **Annex Point/TNsG** **Annex IIIA, XIII.3.4**	**Effects on sediment dwelling organisms** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	This information is only required if the active substance partitions to, and persists in, aquatic sediments such that sediment dwelling organisms are likely to be exposed to the active substance. [redacted]	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.5.1 Annex Point/TNsG Annex IIIA, XIII.3.4	**Effects on sediment dwelling organisms** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

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

Section 7.4.3.5.2 **Annex Point/TNsG** **Annex IIIA, XIII.3.4**	**Aquatic plant toxicity** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [✓]	
Detailed justification:	It is unnecessary to generate data on the effects on increased carbon dioxide to aquatic plants. It should be noted that carbon dioxide plays a vital role in the photosynthesis pathway of plants. It is widely accepted that commercial horticulturists use carbon dioxide to enrich the atmospheres of their greenhouses and other growing environments to accelerate the growth of crops. [redacted]	
Undertaking of intended data submission [ ]	Not applicable.	

Section 7.4.3.5.2 Annex Point/TNsG Annex IIIA, XIII.3.4	**Aquatic plant toxicity** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

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

Section 7.5.1.1 **Annex Point/TNsG** **Annex IIA, VII.7.4**	**Inhibition to microbial activity (terrestrial)** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	There is no mechanism for the carbon dioxide to be released directly into terrestrial systems. Consequently, there will be no increased levels of carbon dioxide in terrestrial systems making it unnecessary to determine the effect of increased carbon dioxide on microbial activity. [redacted]	
Undertaking of intended data submission [ ]	Not applicable	

Section 7.5.1.1 Annex Point/TNsG Annex IIA, VII.7.4	**Inhibition to microbiological activity (terrestrial)** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

Section A7.5.1.2 Annex Point / TNsG Annex IIIA XIII 3.2	**Earthworm, acute toxicity test** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [✓]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	This data is only required if a concern for the terrestrial compartment is indicated by the risk assessment or if there is likely to be long-term exposure to the active substance. Carbon dioxide is to be used as a fumigant insecticide indoors and vented to atmosphere. There will be no increased carbon dioxide levels in the terrestrial system, so it is not necessary to determine the effect of increased carbon dioxide on earthworms. Notwithstanding this, there is a study available in the public domain which gives an indication about the possible effects increased CO_2 may have on cast production by earthworms. This data has been summarised here, for information. No key study available for this data end point that has a reliability indicator of 1 or 2. A study is available which has a reliability indicator of 3. These data can be useful for the risk assessment, so has been included here. It should be noted that it has been demonstrated in Document IIIB, Section 7.1 and Document IIB Section 8.3.4 that under normal conditions of use, there will be no exposure of carbon dioxide to the terrestrial environment when it is used as a fumigant insecticide. There is no mechanism for the carbon dioxide to be released directly into the terrestrial ecosystem because it is a gas. A rudimentary $PNEC_{soil}$ value of 0.03% has been determined for carbon dioxide (i.e. normal atmospheric concentrations of carbon dioxide). [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	

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

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]
1.2.3	**Criteria for data protection**	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No Not carried out to OECD Guideline 207.
2.2	**GLP**	No data
(only where required)		[redacted]
2.3	**Deviations**	Yes This study was not carried out to look at earthworm toxicity *per se* thus did not follow the OECD test guideline 207 (Earthworm acute toxicity tests). This report investigates the activity levels of earthworms exposed to elevated carbon dioxide levels.

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

[redacted]

3.1.4	Composition of product	Not applicable for active substance.
3.1.5	Further relevant properties	Not reported.
3.1.6	Method of analysis	The number of surface casts produced was measured every nine days for a year.
3.2	**Reference substance**	No
3.2.1	Method of analysis for reference substance	Not applicable as reference substance was not used.
3.3	**Testing procedure**	
3.3.1	Preparation of the test substance.	Not applicable. Carbon dioxide is not pre-treated.
3.3.2	Application of the test substance	Carbon dioxide added to soil plots using a screen aided CO_2 control facility (SACC, open top and bottom rings).
3.3.3	Test organisms	Natural population of surface casting earthworms. Species not given.
3.3.4	Test systems	

Artificial soil test substrate	Not relevant as natural soil used: calcareous grassland classified as transition Rendzina, pH 6.5, bulk density on the top soil 1.1g/cm³ well developed, stone free loamy topsoil and a rapid transition at 10 –15cm depth to underlying scree. Depth of Ah-horizon averaged 15cm.
Test mixture	Natural soil compared to the same soil with carbon dioxide added.
Size, volume and material of test container	Not given in this report but in reference by Leadley PW and Korner Ch (1996) in Korner Ch, Bazzaz FA (eds) Carbon dioxide, populations and communities, Academic Press, San Diego pp 159 -175
Amount of artificial soil (kg)/ container	Not given in this report but in reference by Leadley PW and Korner Ch (1996) in Korner Ch, Bazzaz FA (eds) Carbon dioxide, populations and communities, Academic Press, San Diego pp 159 -175
Nominal levels of test concentrations	Control 350µl CO_2/l Test 610µl CO_2/l
Number of replicates/concentration	8
Number of earthworms /test concentration	Not given but natural population
Number of earthworms/container	Not given but natural population
Light source	Natural

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

		Test performed in closed vessels due to significant volatility of test substrate	No. Screen – aided control facility, open top and open bottom rings.	
3.3.5	Test conditions	Test temperature	Mean annual air temperature 8.7°C	
		Moisture content	Mean annual soil water content was 10% greater ($P<0.01$) in elevated CO_2 plots (33% dry mass) than in ambient CO_2 plots (30% dry mass). Mean soil water content measured in treated plots (26.8 ± 0.6% dry mass) over the 6 week long summer dry period in 1995 was significantly ($P<0.05$) greater than that measured in the control plots over the same period (23.3 ± 0.8% dry mass). When averaged over the entire 13- week dry (6 weeks) and subsequent wetter period (7 weeks), soil water content in treated plots was 29.7 ± 0.7% and that in untreated plots was 27.0 ± 0.8% ($p<0.05$).	
		pH	6.5 in soil, no data given throughout experiment.	
		Adjustment of pH	No	
		Light intensity / photo-period	Natural light	
		Relevant degradation products.	No degradation products.	
3.3.6	Test duration	March 1994 to April 1996. 2 years		
3.3.7	Test parameter	Cast production		
3.3.8	Examination	Each 9 days		
3.3.9	Monitoring of test substance concentration	Continuous control except for a period 15 December 1995 to 6 March 1996 when air temperature below freezing or ground covered in snow.		
3.3.10	Statistics	Data analysed using repeated measurement ANOVA's (Sokal and Rohlf 1981 Biometry. The principles and practice of statistics in biological research, 2nd edn,. Freeman, New York and SYSTAT (1992) Statistics, version 5.2 Systat, Evanston.		
		4. RESULTS		
4.1	Filter paper test	Not performed.		
4.1.1	Concentration	Not applicable as filter paper test not performed.		
4.1.2	Number/percentage of animals showing adverse effects	Not applicable as filter paper test not performed.		

Section A7.5.1.2 Earthworm, acute toxicity test
Annex Point IIIA XIII 3.2

4.1.3	Nature of adverse effects	Not applicable as filter paper test not performed,
4.2	**Soil Test**	
4.2.1	Initial concentration of test substance	Treatment maintained at 610 µl CO_2/l.
4.2.2	Effect data (Mortality)	Mortality not measured
4.2.3	Concentration / response curve	Mortality not mentioned
4.2.4	Other effects	Rates of surface cast production expressed as g/m/day in communities with elevated CO_2 were up to 6 times higher than those in ambient CO_2. Cumulative surface cast production after 1 year was 35% greater in communities with elevated CO2 than those in ambient CO2. CO2 induced stimulation of earthworms increased soil turnover. CO2 induced stimulation of earthworms increased N and C cycling.
4.3	**Results of controls**	
4.3.1	Mortality	Not reported
4.3.2	Number/percentage of earthworms showing adverse effects	Not reported
4.3.3	Nature of adverse effects	Not applicable
4.4	**Test with reference substance**	Not performed
4.4.1	Concentration	Not required
4.4.2	Results	Not required

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

This study was not carried out to Guideline C.8 in Annex V of Directive 67/548/EEC or to to OECD Guideline 207. Rather than looking at acute toxicity *per se*, this report investigates the effects on cast production of an increased concentration of carbon dioxide.

Using a screen aided CO_2 control facility 1.2m^3 plots of grassland on a south west facing slope at an elevation of around 515m near a village of Nenzlingen in the Jura Mountains of Switzerland were set up. Eight were maintained at ambient CO_2 concentrations (350µl CO_2/l) and eight at elevated CO_2 (610µl CO_2/l). Cumulative earthworm surface cast production was measured 40 times over 1 year. Precipitation and soil temperature were continuously monitored. Vegetation from each plot was harvested down to 5cm height in June and October and dried at 80°C for 48 hours, plant dry mass was then calculated. Total C and N content of

Section A7.5.1.2 Earthworm, acute toxicity test
Annex Point IIIA XIII 3.2

		dried pulverised cast samples from each plot was measured with a CHN analyzer. Inorganic C content was measured using HCL digestion and a carbonate carbon analyser. The organic content of the casts was measured by subtracting the inorganic C from the total C.
5.2	**Results and discussion**	Cast production over 1 year was 35% greater in elevated carbon dioxide compared to ambient. Elevated CO_2 had no influence on the seasonality of earthworm activity. There was correlation between soil water content and cast production. No correlation was found between activity and soil temperature or plant biomass productivity. No CO_2 related differences were found in total N and organic carbon concentration of surface casts. The increase in earthworm activity corresponded to a 30% increase of the amount of N and organic carbon eggested by the worms. There is an indirect stimulatory effect of elevated atmospheric carbon dioxide on earthworm activity which may have effects on ecosystem function and plant community structure in the long term.
5.2.1	LC_0	Not reported
5.2.2	LC_{50}	Not reported
5.2.3	LC_{100}	Not reported
5.3	**Conclusion**	This report does not look at toxicity of carbon dioxide to earthworms however it gives an indication of effects of increased CO_2 levels on their activity.
5.3.1	Other conclusions	
5.3.2	Reliability	3
5.3.2	Deficiencies	Yes This study was not carried out to Guideline C.8 in Annex V of Directive 67/548/EEC or to to OECD Guideline 207. Rather than looking at acute toxicity *per se*, this report investigates the effects on cast production of an increased level of carbon dioxide.

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	*Adopt applicant's version or include revised version. If necessary, discuss relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version, If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator (the text in section 4.4.2.5.1 gives guidance on this point)*
Acceptability	Acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliable indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	COMMENTS FROM
Date	*Give date of the 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*

Section A7.5.1.3 Annex Point / TNsG Annex IIIA XIII 3.4	**Acute Toxicity to Plants** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	This information is only required if a concern for the terrestrial compartment is indicted by the risk assessment or if there is likely to be long term exposure to the active substance. Carbon dioxide in this case is used in a closed system, indoors and finally vented to atmosphere. Consequently there will be no increased carbon dioxide levels in the terrestrial system and so it is not necessary to determine the effect of increased carbon dioxide in plants. Notwithstanding the above, it should be noted that carbon dioxide plays a vital role in the photosynthesis pathway of plants. It is widely accepted that commercial horticulturists, such as tomato growers, use carbon dioxide to enrich the atmospheres of their greenhouses to accelerate the growth of their crops. [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	

Section A7.5.2.1 Annex Point / TNsG Annex IIIA XIII 3.2	**Reproduction Study with Earthworms or Other Soil Non-target Macro-organisms** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	This information is only required if a concern for the terrestrial compartment is indicted by the risk assessment or if there is likely to be long term exposure to the active substance. Carbon dioxide in this case is used in a closed system, indoors and finally vented to atmosphere. Consequently there will be no increased carbon dioxide levels in the terrestrial system and so it is not necessary to determine the effect of increased carbon dioxide in plants. . [redacted]	
Undertaking of intended data submission [ ]	Not applicable.	

Section A7.5.2.1 Annex Point / TNsG Annex IIIA XIII 3.2	**Reproduction Study with Earthworms or Other Soil Non-target Macro-organisms** Section 7: Ecotoxicological Profile, including Fate and Behaviour

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

Section A7.5.2.2 Annex Point / TNsG Annex IIIA XIII 3.4	**Long-term Test with Terrestrial Plants** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	This information is only required if a concern for the terrestrial compartment is indicted by the risk assessment or if there is likely to be long term exposure to the active substance. Carbon dioxide in this case is used in a closed system, indoors and finally vented to atmosphere. Consequently there will be no increased carbon dioxide levels in the terrestrial system and so it is not necessary to determine the effect of increased carbon dioxide in plants. [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	

Section A7.5.3.1.1. Annex Point / TNsG Annex IIIA XIII 1.1	**Acute Oral Toxicity – Birds** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [✔]	**Technically not feasible** [✔] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	An acute oral toxicity study for carbon dioxide cannot be submitted because it is not technically possible to determine the acute toxicity of carbon dioxide by the oral route. This is because there is no approved guideline for testing the acute toxicity of a gas by the oral route. Notwithstanding the above, it should be noted that carbon dioxide is constantly produced by all birds as a result of the numerous metabolic reactions involving carbon-containing compounds. Broiler chickens in a healthy barn environment can produce up to 60 litres CO_2 /bird/day without causing any toxic effects. (See attached study summary for details). Carbon dioxide is recognised as a humane method for the dispatch of birds and small mammals. As shown in the attached study summary, the UK Home Office recommends that a rising concentration of carbon dioxide be used to dispatch birds up to 1.5% in weight. In atmospheres containing 30% carbon dioxide, the bird will lose consciousness and at 70% death will occur.	
Undertaking of intended data submission [ ]	Not applicable.	

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

Section A7.5.3.1.1 Acute Oral Toxicity on Birds (1 of 2)

Annex Point IIIA, XIII, 1.1

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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 SETAC procedures (as advised in 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).

2.2 GLP No.

GLP was not compulsory at the time study was performed.

2.3 Deviations Yes.

No set guideline followed.

3. METHOD

3.1 Test material [redacted]

3.1.1. Lot/Batch number [redacted]

3.1.2 Specification [redacted]

[redacted]

3.2	**Administration of the test substance**	Refer to table A7.5.3.1.1-1, at the end of this study summary. However, note that study simply reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space.
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	Not applicable. Reference substance was not used.
3.4	**Testing procedure**	
3.4.1	Test organisms	Refer to table A7.5.3.1.1-2, at the end of this study summary.
3.4.2	Test system	Refer to table A7.5.3.1.1-3, at the end of this study summary.
3.4.3	Diet	Not reported, however note that the test substance not administered in the diet. (Refer to table A7.5.3.1.1-1, at the end of this study summary for details).
3.4.4	Test conditions	No data available on test conditions (such as temperature, shielding of animals, ventilation, humidity and photoperiod/lighting).
3.4.5	Duration of test	Carbon dioxide production by birds, via respiration, was measured for 35 days.
3.4.6	Test parameter	Not applicable. Study reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space. Parameters such as mortality, abnormal behaviour or signs of intoxication were not studied.
3.4.7	Examination / Observation	Carbon dioxide production per day, was reported for birds weekly, for 5 weeks on days 1, 7, 14, 21, 28 and 35.
3.4.8	Statistics	No calculations or statistics applied. Carbon dioxide production by birds was reported as litres carbon dioxide per 10,000 birds, per day.
		4. RESULTS
4.1	**Limit test / Range finding test**	Not performed.
4.2	**Results test substance**	
4.2.1	Applied concentrations	Carbon dioxide is naturally produced by birds, by the process of respiration. Each bird respires carbon dioxide into the air, where it is inhaled by other birds in the environment. Carbon dioxide production by birds is reported in table A7.5.3.1.1-4, at the end of this study summary.
4.2.2	Effect data (Mortality)	Not applicable. Study reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space. Parameters such as mortality, abnormal behaviour or signs of intoxication were not studied.
4.2.3	Body weight	Body weights not reported. Results were expressed for birds of different ages (see table A7.5.3.1.1-4, at the end of this study summary).
4.2.4	Feed consumption	Not reported.

Section A7.5.3.1.1 **Acute Oral Toxicity on Birds (1 of 2)**
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4.2.5	Concentration / response curve	Not applicable. Study reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space. Parameters such as mortality, abnormal behaviour or signs of intoxication were not studied.
4.2.6	Other effects	None reported.
4.3	**Results of controls**	
4.3.1	Number / percentage of animals showing adverse effects	Not applicable. Study reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space. Parameters such as mortality, abnormal behaviour or signs of intoxication were not studied.
4.3.2	Nature of adverse effects	Not applicable. Study reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space. Parameters such as mortality, abnormal behaviour or signs of intoxication were not studied.
4.3	**Test with reference substance**	Not performed.
		5. APPLICANTS SUMMARY AND CONCLUSION
5.1	**Materials and Methods**	This study was not carried out to SETAC procedures (as advised in 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). Study reports typical volume of carbon dioxide added to air, by broiler chickens in a barn environment (when housed for farming e.g. for egg production). This report is simply advice about the minimum, good quality ventilation required to control carbon dioxide levels for a healthy barn environment.
5.2	**Results and discussion**	As shown in table A7.5.3.1.1-4, at the end of this study summary, broiler chickens in a healthy barn environment can produce up to 60 litres carbon dioxide / bird / day without causing toxic effects.
5.3	**Conclusion**	This data has been supplied to demonstrate the levels of carbon dioxide that chickens, when intensively farmed, are exposed to daily. Therefore validity criteria according to EPA OPPTS 850.2100 is not relevant for this study.
5.3.1	Reliability	4
5.3.2	Deficiencies	Yes Study reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space. It is duly acknowledged that there is insufficient reporting of methods used in this study, and the results. In addition, this data has not been generated in accordance with scientifically acceptable protocols. Despite the major reporting deficiencies in this study, it gives an indication about the level of carbon dioxide that can be tolerated by birds in a barn environment (when housed for farming e.g. egg production).

Section A7.5.3.1.1 Acute Oral Toxicity on Birds (1 of 2)

Annex Point IIIA, XIII, 1.1

Table A7_5_3_1_1-1 Method of administration of the test substance

Carrier/vehicle	Details
Water	No
Organic carrier	No
Concentration of the carrier (% v/v)	Carrier not used. See "Administration of test substance" (below).
Other vehicle	Vehicle not used. See "Administration of test substance" (below).
Function of carrier/ vehicle	Carrier/ vehicle not used. See "Administration of test substance" (below).
Administration of test substance	Carbon dioxide is naturally produced by birds, by the process of respiration. Each bird respires carbon dioxide into the air, where it is inhaled by other birds in the environment.

Table A7_5_3_1_1-2 Test animals

Criteria	Details
Species / strain	Broiler chicken.
Source	Not reported.
Age (in weeks), sex and initial body weight (bw)	Sex and body weight not reported. Age of birds were: 1 day old 1 week old 2 weeks old 3 weeks old 4 weeks old 5 weeks old.
Breeding population	Not reported.
Amount of food	Not reported.
Age at time of first dosing	Study simply reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space. Measurements were taken from birds aged 1 day old.
Health condition / medication	Not reported.

Section A7.5.3.1.1 Acute Oral Toxicity on Birds (1 of 2)

Annex Point IIIA, XIII, 1.1

Table A7_5_3_1_1-3 Test system

Criteria	Details
Test location	Indoors, in a barn environment (when housed for farming e.g. for egg production).
Holding pens	Not used.
Number of animals	Number of animals tested has not been reported but results expressed per 10,000 birds.
Number of animals per pen (cm^2/bird)	Not reported, but minimum permitted space allowed is 23.77 cm^2/ bird (0.78 ft^2/bird).
Number of animals per dose	Not applicable. Study reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space.
Pre-treatment / acclimation	Not applicable. Study reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space.
Diet during test	Not reported.
Dosage levels (of test substance)	Not applicable. Study reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space.
Replicate/dosage level	Number of replicate measurements of carbon dioxide production by birds (if any) has not been reported.
Feed dosing method	Not applicable. Study reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space.
Dosing volume per application	Not applicable. Study reports levels of carbon dioxide produced by birds, through respiration, in an enclosed space.
Frequency, duration and method of animal monitoring after dosing	Observations / animal monitoring not reported.
Time and intervals of body weight determination	Body weights not reported.

Section A7.5.3.1.1 Acute Oral Toxicity on Birds (1 of 2)

Annex Point IIIA, XIII, 1.1

Table A7_5_3_1_1-4 Test results: Carbon dioxide Production by Broiler Chickens in a barn environment

Bird age	Carbon dioxide production / day per 10,000 birds
Day 1	57,000 L/ day (equivalent to 5.7 L CO_2/bird/day)
Day 7 (1 week)	107,000 L/ day (equivalent to 10.7 L CO_2/bird/day)
Day 14 (2 weeks)	200,000 L/ day (equivalent to 20 L CO_2/bird/day)
Day 21 (3 weeks)	320,000 L/ day (equivalent to 32 L CO_2/bird/day)
Day 28 (4 weeks)	455,000 L/ day (equivalent to 45.5 L CO_2/bird/day)
Day 35 (5 weeks)	600,000 L/ day (equivalent to 60 L CO_2/bird/day)

Section A7.5.3.1.1 Acute Oral Toxicity on Birds (1 of 2)

Annex Point IIIA, XIII, 1.1

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

Section A7.5.3.1.1 Acute Oral Toxicity on Birds (2 of 2)

Annex Point IIIA, XIII, 1.1

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1. REFERENCE

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

2. GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Not applicable. [redacted]
2.2	**GLP**	Not applicable. Refer to "2.1 Guideline Study" (above).
2.3	**Deviations**	Not applicable. Refer to "2.1 Guideline Study" (above).

3. METHOD

3.1	**Test material**	As given in section 2.
3.1.1.	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.2	**Administration of the test substance**	Refer to table A7.5.3.1.1-1, at the end of this study summary.
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	Not applicable. Reference substance was not used.

Section A7.5.3.1.1 Acute Oral Toxicity on Birds (2 of 2)

Annex Point IIIA, XIII, 1.1

3.4	**Testing procedure**	
3.4.1	Test organisms	Refer to table A7.5.3.1.1-2, at the end of this study summary.
3.4.2	Test system	Refer to table A7.5.3.1.1-3, at the end of this study summary.
3.4.3	Diet	Not reported, however note that the test substance not administered in the diet. (Refer to table A7.5.3.1.1-1, at the end of this study summary for details).
3.4.4	Test conditions	Refer to table A7.5.3.1.1-3, at the end of this study summary.
3.4.5	Duration of test	Birds and small animals become unconscious when the rising carbon dioxide concentration reaches 30%, and they die when it reaches 70 % v/v. Typical timescales to reach these concentrations have not been reported, because it depends on size of the enclosed chamber.
3.4.6	Test parameter	Mortality.
3.4.7	Examination / Observation	Not reported.
3.4.8	Statistics	No calculations or statistics applied.
		4. RESULTS
4.1	**Limit test / Range finding test**	Not performed.
4.2	**Results test substance**	
4.2.1	Applied concentrations	70% v/v carbon dioxide (which causes death of test animals).
4.2.2	Effect data (Mortality)	Mortality data expressed as a percent of exposed animals has not been reported. [redacted]
4.2.3	Body weight	Recommendations are for birds and small mammals up to 1.5 kg in weight.
4.2.4	Feed consumption	Feed consumption of test animals has not been reported. Refer to "4.2.2 Effects Data (Mortality)" for explanation.
4.2.5	Concentration / response curve	Not reported. Refer to "4.2.2 Effects Data (Mortality)" for explanation.
4.2.6	Other effects	Inhalation of higher concentrations of carbon dioxide produces a slightly irritant or fizzy sensation in the nasal mucous membrane as the gas goes into solution. A rising blood concentration has a direct effect on the brain producing unconsciousness, first stimulating then depressing the rate of breathing. The initial stimulation of breathing first enhances the uptake of the gas. Unconsciousness is due to the direct narcotic effect of carbon dioxide rather than hypoxia resulting from the lowered oxygen content in the inspired air. Induction of narcosis is faster in smaller laboratory animals and therefore causes less distress. For this reason, exposure of carbon dioxide in a rising concentration is recommended as a humane method of killing rodents, rabbits and birds up to 1.5 kg body weight. Note that although death of animals occurred when the carbon dioxide concentration reached 70% v/v, unconsciousness was

observed as the rising carbon dioxide concentration reached 30% v/v.

4.3	**Results of controls**	
4.3.1	Number / percentage of animals showing adverse effects	Results of control animals has not been reported. [redacted]
4.3.2	Nature of adverse effects	Not applicable. Refer to "4.3.1 Number / percentage of animals showing adverse effects" for explanation.
4.3	**Test with reference substance**	Not performed.

5. APPLICANTS SUMMARY AND CONCLUSION

5.1 Materials and Methods

[redacted] following method as a means to humanely kill birds and small mammals (up to 1.5 kg in weight) after scientific procedures or when kept in breeding or supply establishments.

A simple chamber with a lid and a means to introduce a controlled flow of carbon dioxide can be used. The animal is placed in the empty chamber and the carbon dioxide, being heavier than air, will accumulate at the lower level. Animals may be left in the chamber until rigor mortis is observed, or removed and death ensured by exsanguination or neck dislocation. The chamber should be emptied, flushed clear of residual carbon dioxide and cleaned after each batch of animals has been killed.

5.2 Results and discussion

[redacted] dispatch birds and other small mammals up to 1.5 kg in weight. In atmospheres containing 30% carbon dioxide, the bird (or other small mammal) will lose consciousness and at 70% death will occur.

5.3 Conclusion

[redacted] for humane methods for killing of birds and small mammals after scientific procedures or when kept in breeding or supply establishments. [redacted]
Therefore validity criteria according to EPA OPPTS 850.2100 is not relevant for this study.

Section A7.5.3.1.1 Acute Oral Toxicity on Birds (2 of 2)

Annex Point IIIA, XIII, 1.1

5.3.1	Reliability	4
5.3.2	Deficiencies	Yes

[redacted] gives recommendations for humane methods for killing of birds and small mammals after scientific procedures or when kept in breeding or supply establishments. It recommends exposure of 70% v/v carbon dioxide as a method to humanely kill birds and small animals.

It is duly acknowledged that there is insufficient reporting of methods used in this study, and the results. In addition, this data has not been generated in accordance with scientifically acceptable protocols.

Despite the major reporting deficiencies in this study, it gives an indication about the level of carbon dioxide that kills birds (up to 1.5 kg in weight).

This study, notwithstanding it's deficiencies, can be used to support the inhalation toxicity of carbon dioxide because under normal conditions of use, the use of carbon dioxide in Rentokil Initial's rodenticide (PT14) products will not cause any elevation in the level of carbon dioxide in air, outside normal atmospheric ranges.

Section A7.5.3.1.1 Acute Oral Toxicity on Birds (2 of 2)

Annex Point IIIA, XIII, 1.1

Table A7_5_3_1_1-1 Method of administration of the test substance

Carrier/vehicle	Details
Water	No
Organic carrier	No
Concentration of the carrier (% v/v)	Carrier not used. See "Administration of test substance" (below).
Other vehicle	Vehicle not used. See "Administration of test substance" (below).
Function of carrier/ vehicle	Carrier/ vehicle not used. See "Administration of test substance" (below).
Administration of test substance	Carbon dioxide is pumped into an enclosed chamber, where it is inhaled by the test bird.

Table A7_5_3_1_1-2 Test animals

Criteria	Details
Species / strain	Rodents, rabbits and birds.
Source	Not applicable. [redacted]
Age (in weeks), sex and initial body weight (bw)	Method is recommended for rodents, rabbits and birds up to 1.5 kg in weight.
Breeding population	Not reported. Refer to "source" (above) for explanation.
Amount of food	Not reported. Refer to "source" (above) for explanation.
Age at time of first dosing	Not reported. Refer to "source" (above) for explanation.
Health condition / medication	Not reported. Refer to "source" (above) for explanation.

Section A7.5.3.1.1 Acute Oral Toxicity on Birds (2 of 2)

Annex Point IIIA, XIII, 1.1

Table A7_5_3_1_1-3 Test system

Criteria	Details
Test location	A simple chamber with a lid and a means to introduce a controlled flow of carbon dioxide.
Number of animals	One animal per chamber.
Number of animals per dose	Not reported. [redacted]
Pre-treatment / acclimation	No pre-treatment or acclimation. [redacted]
Diet during test	Not reported. Refer to "Number of animals per dose" (above) for explanation.
Dosage levels (of test substance)	Not reported. Refer to "Number of animals per dose" (above) for explanation.
Replicate/dosage level	Not reported. Refer to "Number of animals per dose" (above) for explanation.
Feed dosing method	Not applicable. Refer to "Number of animals per dose" (above) for explanation.
Dosing volume per application	Not applicable. Refer to "Number of animals per dose" (above) for explanation.
Frequency, duration and method of animal monitoring after dosing	Observations of the animals in the test chamber have been reported (see "4.2.6 Other effects" in study summary), but frequency, duration and method of animal monitoring have not been reported.
Time and intervals of body weight determination	Not reported. Refer to "Number of animals per dose" (above) for explanation.

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	

Section A7.5.3.1.2. Annex Point / TNsG Annex IIIA XIII 1.2	**Short Term Toxicity –Birds** Section 7: Ecotoxiological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [✓]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	It should be noted that carbon dioxide is constantly produced by all birds as a result of the numerous metabolic reactions involving carbon-containing compounds. Broiler chickens in a healthy barn environment can produce up to 60 litres CO_2 /bird/day without causing any toxic effects[1]. 1. Refer to study summary submitted under section A7.5.3.1.1 Acute Oral Toxicity – Birds, for details.	
Undertaking of intended data submission [ ]	Not applicable.	

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

Section A7.5.3.1.3. Annex Point / TNsG Annex IIIA XIII 1.3	**Effects on Reproduction – Birds** Section 7: Ecotoxiological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [✓]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	It should be noted that carbon dioxide is constantly produced by all birds as a result of the numerous metabolic reactions involving carbon-containing compounds. Broiler chickens in a healthy barn environment can produce up to 60 litres CO_2 /bird/day without causing any toxic effects[1]. 1. Refer to study summary submitted under section A7.5.3.1.1 Acute Oral Toxicity – Birds, for details.	
Undertaking of intended data submission [ ]	Not applicable.	

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

Section A7.5.4.1 Annex Point / TNsG Annex IIIA XIII 3.1	**Acute Toxicity to Honeybees and other Beneficial Arthropods** Section 7: Ecotoxiological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	It should be noted that carbon dioxide is constantly produced by arthropods as a result of the numerous metabolic reactions involving carbon-containing compounds, without causing any toxic effects.	
Undertaking of intended data submission [ ]	Not applicable.	

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

Section A7.5.5 Annex Point / TNsG Annex IIA, VII 7.5	**Bioconcentration, Terrestrial** Section 7: Ecotoxiological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	Carbon dioxide is naturally present in the soil. It is constantly produced by soil-dwelling organisms as a result of the numerous metabolic reactions involving carbon-containing compounds[1]. Carbon dioxide is also naturally produced in the soil during the process of decomposition[1]. Soil dwelling organisms are exposed to carbon dioxide in the soil without any toxic effects. [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	

Section A7.5.5.1 Annex Point / TNsG Annex IIA, VII 7.5	**Bioconcentration, Further Studies** Section 7: Ecotoxiological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	Carbon dioxide is naturally present in the soil. It is constantly produced by soil-dwelling organisms as a result of the numerous metabolic reactions involving carbon-containing compounds[1]. Carbon dioxide is also naturally produced in the soil during the process of decomposition[1]. Soil dwelling organisms are exposed to carbon dioxide in the soil without any toxic effects. [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	

Section A7.5.6 Annex Point / TNsG Annex IIIA XIII 3.4	**Effects on Other Terrestrial Non-Target Organisms** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	This information is only required if a concern for the terrestrial compartment is indicted by the risk assessment or if there is likely to be long term exposure to the active substance. Consequently there will be no increased carbon dioxide levels in the terrestrial system so it is not necessary to determine the effect of increased carbon dioxide on terrestrial non-target organisms. [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	

Section A7.5.7.1 **Annex Point / TNsG** **Annex IIIA XIII 3.4**	**Effects on Mammals** Section 7: Ecotoxicological Profile, including Fate and Behaviour	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [✓]	
Detailed justification:	This information is only required if a concern for the direct/indirect exposure for mammals is possible, and there is a severe risk for the terrestrial environment. Carbon dioxide is used indoors within a sealed fumigation bubble in situations where exposure to mammals will not be expected to occur. There will be no increased carbon dioxide levels in the terrestrial system so it is not necessary to determine the effect of increased carbon dioxide to mammals. Given the above justification, it is not necessary to submit data to meet the following data end points: 7.5.7.1.1 Acute oral toxicity (mammals) 7.5.7.1.2 Short term toxicity (mammals) 7.5.7.1.3 Effects on reproduction (mammals) Note that these points have been addressed for carbon dioxide in Section 6 Toxicological and Metabolic Studies. Further studies are not required.	
Undertaking of intended data submission [ ]	Not applicable.	

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

Section A7.6 Summary of ecotoxicological effects and fate and behaviour in the environment.

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

4 ENVIRONMENTAL EFFECTS ASSESSMENT

4.1 FATE AND DISTRIBUTION IN THE ENVIRONMENT

4.1.1 Degradation

4.1.1.1 Biodegradation (1 of 2)

Guideline / Test method	Test type	Test parameter	Inoculum			Additional substrate	Test substance conc.	Degradation		Remarks	Reference
			Type	Conc	Adaptation			Incubation period	Degree [%]		
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Ready Biodegradability [1] Carbon dioxide does break down in water to give carbonic acid: $CO_2 + H_2O \surd H_2CO_3$ This, however, is not brought about by biological means, as it will happen as the result of the 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.	Document III-A Section 7.1.1.2.1
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Inherent Biodegradability [1] Inherent biodegradability is technically not possible to perform on carbon dioxide as the test methods are designed to work with water-soluble, non volatile organic substances. Carbon dioxide, although water soluble, is volatile and inorganic.	Document III-A Section 7.1.1.2.2

Footnotes

1. Due to the ready biodegradability and inherent biodegradability of carbon dioxide, it is not scientifically necessary to determine the rate and route of carbon dioxide degradation in aquatic systems (the data end points detailed in Document III-A, 7.1.2, 7.1.2.2.1 and 7.1.2.2.1).

4.1.1.1 Biodegradation (2 of 2)

Guideline / Test method	Test type	Test parameter	Inoculum			Additional substrate	Test substance conc.	Degradation		Remarks	Reference
			Type	Conc	Adaptation			Incubation period	Degree [%]		
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<u>Biodegradation in sea water</u> Data on 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 carbon dioxide be used as a biocide in a closed system.	Document III-A Section 7.1.1.2.3
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<u>Biological sewage treatment – aerobic and anaerobic biodegradation</u> Aerobic biodegradation in biological sewage treatment is not applicable, as carbon dioxide is not intended to enter sewage treatment plants before release to the environment.	Document III-A Section 7. 1.2.1.1 Document III-A Section 7.1.2.1.2

4.1.1.2 Abiotic Degradation

Hydrolysis

Guideline /Test Method	pH	Temperature [°C]	Initial TS concentration C_0 [mol/l]	Reaction rate Constant, K_h [1/s x 10^5]	Half-life, DT_{50} [h]	Coefficient of correlation, r_2	Remarks	Reference
N/A	N/A	N/A	N/A	N/A	N/A	N/A	Further work or studies are not considered 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, 88 ml of carbon dioxide will dissolve in 100 ml of water Some of this dissolved carbon dioxide will react with water to form carbonic acid. $CO_2 + H_2O \surd H_2CO_3$ Carbonic acid will undergo further reactions to produce bicarbonate and carbonate ions $H_2CO_3 + OH^- \surd HCO^-_3 + H_2O$ $HCO^-_3 + OH^- \surd CO_3^{2-} + H_2O$ 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. The equilibrium constant for the disassociation reaction is 600, which means that there is 600 times more carbon dioxide in solution than is converted to carbonic acid. This will not change with time, so carbon dioxide can be considered to be hydrolytically stable. It should be noted that each of the reactions described above is reversible and an equilibrium will exist for each. The introduction or removal of even a tiny amount of any of the chemical species in the reactions described will cause the equilibria to be disturbed and change the concentrations of all the chemical species in the reaction. 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 be accurately measured without removing them from the system and thus disturbing the	Document III-A Section 7.1.1.1.1

							equilibria.	

Photolysis in water

Guideline/ Test Method	Initial Molar TS concentration	Total Recovery of Test Substance [% of appl. a.s.]	Photolysis rate constant (k^c_p)	Direct photolysis sunlight rate constant (K_{pE})	Reaction quantum yield (0^c_E)	Half-life ($t_{1/2E}$)	Remarks	Reference
N/A	N/A	N/A	N/A	N/A	N/A	N/A	The US EPA method entitled Fate, Transport and Transformation Test Guidelines OPPTS 835.2210 Direct Photolysis Rate in Water by Sunlight states that the test method is applicable to all chemicals which have a UV/absorption maxima in the range of 290-800nm. Carbon dioxide has a UV absorption maxima of [redacted] and as such this test is not technically feasible to perform.	Document III-A Section 7.1.1.1.2

Phototransformation in air

Guideline/ Test Method	Initial Molar TS concentration	Total Recovery of Test Substance [% of appl. a.s.]	Photolysis rate constant (k^c_p)	Direct photolysis sunlight rate constant (K_{pE})	Reaction quantum yield (0^c_E)	Half-life ($t_{1/2E}$)	Remarks	Reference
N/A	N/A	N/A	N/A	N/A	N/A	N/A	As a gas under all environmental conditions that are likely to occur on earth, carbon dioxide will occur predominately in air. Carbon dioxide is a by-product of aerobic respiration There is a natural "carbon cycle" whereby carbon dioxide is continuously added and removed from the environment through natural processes. Under normal conditions of use, the carbon dioxide used in Rentokil Initial's rodenticide (PT14) products that contain carbon dioxide will not cause any elevation in the level of carbon dioxide in air, outside normal atmospheric ranges. This makes it unnecessary to determine the fate of carbon dioxide in air.	Document III-A Section 7.3.1 Document III-A Section 7.3.2

4.1.1.3 Distribution

Absorption onto/desorption from soils (1 of 2)

Guideline/ test method	Absorbed a.s. [%]	K_a [1]	K_{aOC} [2]	K_d [3]	K_{dOC} [4]	K_a / K_d [5]	Degradation products		Remarks	Reference
							Name	[%] of a.s.		
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	In water, carbon dioxide breaks down to give carbonic acid, which is brought about by the result of simple dissolution of the carbon dioxide in water. $CO_2 + H_2O \surd H_2CO_3$ It will attain equilibrium with air spaces in soil through passive diffusion. The carbon dioxide used here is not applied directly to the sediment. For the reasons detailed above, it is not necessary to conduct a adsorption/desorption screening test for carbon dioxide.	Document III-A Section 7.1.3 Document III-A Section 7.1.4 Document III-A Section 7.1.4.1

Key

1. K_a = Adsorption coefficient.
2. K_{aOC} = Adsorption coefficient based on organic carbon content.
3. K_d = Desorption coefficient.
4. K_{dOC} = Desorption coefficient based on organic carbon content.
5. K_a/K_d = Adsorption/desorption distribution coefficient.

Absorption onto/desorption from soils (2 of 2)

Guideline/ test method	Absorbed a.s. [%]	K_a [1]	K_{aOC} [2]	K_d [3]	K_{dOC} [4]	K_a / K_d [5]	Degradation products Name	Degradation products [%] of a.s.	Remarks	Reference
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<u>Additional soil studies (as detailed in data requirements 7.2.1, 7.2.2, 7.2.2.1, 7.2.2.2, 7.2.2.3, 7.2.2.4, 7.2.3, 7.2.3.1, 7.2.3.2)</u> Data fate and behaviour in soil is not required as carbon dioxide is not intended to be either used or released directly to the soil and therefore these studies are not required. The data end points for ready biodegradability (7.1.1.2.1) and inherent biodegradability (7.1.1.2.2) do not indicate the need to conduct studies on the fate and behaviour of carbon dioxide in soil. In addition, this is substantiated by the fact that that carbon dioxide does undergo a degree of abiotic degradation by means of simple dissolution in water. Also, it is well known that although carbon dioxide occurs predominately in air, it will attain equilibrium with air spaces in soil through passive diffusion.	Document III-A Section 7.2.1 7.2.2 7.2.2.1, 7.2.2.2, 7.2.2.3, 7.2.2.4, 7.2.3, 7.2.3.1, 7.2.3.2
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<u>Bioconcentration in soil</u> The carbon dioxide used here is not applied directly to the sediment. Carbon dioxide is naturally present in the soil. It is constantly produced by soil-dwelling organisms as a result of the numerous metabolic reactions involving carbon-containing compounds. Carbon dioxide is also naturally produced in the soil during the process of decomposition. Soil dwelling organisms are exposed to carbon dioxide in the soil without any toxic effects.	Document III-A Section A7.5.5 Document III-A Section A7.5.5.1

Key

1. K_a = Adsorption coefficient.
2. K_{aOC} = Adsorption coefficient based on organic carbon content.
3. K_d = Desorption coefficient.
4. K_{dOC} = Desorption coefficient based on organic carbon content.
5. K_a/K_d = Adsorption/desorption distribution coefficient.

4.1.2 Accumulation

Measurements of aquatic bioconcentration

Guideline /Test method	Exposure	Log Pow of a.s.	Initial concentration of a.s.	Steady-state BCF	Uptake rate constant	Depuration rate constant	Depuration time (DT_{50})	Metabolites	Remarks	Reference
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	"Bioconcentration" is the process leading to a higher concentration of, for example, a pesticide in an organism than in environmental media to which it is exposed. Since CO_2 is a naturally occurring substance that all living organisms are exposed to, and which plays a vital role in the normal maintenance of life, studies into the bioconcentration of carbon dioxide are not justified. The partition coefficient of CO_2 is 0.83.	Document III-A Section 7.4.2

Estimations on aquatic bioconcentration

Basis for estimation	Log Pow (measured)	Estimated BCF for fish (freshwater)	Estimated BCF for fish eating bird/predator	Remarks	Reference
N/A	N/A	N/A	N/A	"Bioconcentration" is the process leading to a higher concentration of, for example, a pesticide in an organism than in environmental media to which it is exposed. Since CO_2 is a naturally occurring substance that all living organisms are exposed to, and which plays a vital role in the normal maintenance of life, studies into the bioconcentration of carbon dioxide are not justified. The partition coefficient of CO_2 is 0.83.	Document III-A Section 7.4.2

Estimation on terrestrial bioconcentration

Basis for estimation	Log Pow (measured)	Estimated BCF for				Remarks	Reference
		Terrestrial food chain I		Terrestrial food chain II			
		Soil dwelling species	Predatory bird /vertebrate	Terrestrial plant	Grazing non-target organism		
N/A	N/A	N/A	N/A	N/A	N/A	"Bioconcentration" is the process leading to a higher concentration of, for example, a pesticide in an organism than in environmental media to which it is exposed. Since CO_2 is a naturally occurring substance that all living organisms are exposed to, and which plays a vital role in the normal maintenance of life, studies into the bioconcentration of carbon dioxide are not justified. The partition coefficient of CO_2 is 0.83.	Document III-A Section 7.4.2

4.2 EFFECT ON ENVIRONMENTAL ORGANISMS

4.2.1 Aquatic compartment

Acute toxicity to fish

Guideline/ Test method	Species	Endpoint/ Type of test	Exposure Design	Duration	Results LC_0 LC_{50} LC_{100}	Remarks	Reference
No set guideline followed. Refer to "Exposure Design" for summary of methodology followed.	Brook Trout (*Salvelinus fontinalis)* Slimy Sculpin (*Cottus cognatus*) Blacknose dace (*Rhinichthys atratulus)*	Rather than looking at acute toxicity *per se*, this test investigated the physiological and behavioural effects of fish exposed to carbon dioxide.	3 replicates of 4 different CO_2 levels were tested in treatment vessels. Dose levels of CO_2 were 1.4%, 2.8% and 5.1%. Substrate cover of flat creekbed stones (5-15 cm) was provided in each tank; floe maintained at 6 l/min and water volume 85 l. CO_2 was measured throughout the test period, and adjustments made periodically to maintain treatments at or near prescribed points. After tests, fish were monitored for 1 week to assess short-term mortality.	24 h	Rather than looking at acute toxicity *per se,* this test investigated the physiological and behavioural effects of fish exposed to carbon dioxide. The results show that physiological responses to exposure to increased carbon dioxide in fish differed by species when they were exposed to 1.4%, 2.8% and 5.1% CO_2. However recovery to pre-treatment activity rates of most behaviour patterns (including feeding) was observed 24h after cessation of exposure in all 3 test species.	This study gives an indication about the possible physiological and behavioural effects increased levels of CO_2 may have on fish. This study, notwithstanding it's deficiencies, can be used to support the acute toxicity of CO_2 to fish because under normal conditions of use, the use of CO_2 as a fumigant insecticide will not cause any elevation in the level of CO_2. Given this, it makes it unnecessary to conduct further studies on the toxicity of CO_2 to fish. [1,2,3]	Document III-A Section 7.4.1.1

Footnotes

1. Due to the results available on the acute toxicity of carbon dioxide to fish, coupled with the fact that there is no exposure to the aquatic environment, it is not necessary to submit further studies on the effects of carbon dioxide to aquatic organisms (the data requirements detailed in Document III-A, 7.4.3). It is also not necessary to submit data on prolonged toxicity of carbon dioxide to fish (Document III-A, 7.4.3.1).

2. Due to the results available in the core base set of environmental toxicity data for carbon dioxide, particularly that available on the acute toxicity to fish and the fact that there is no exposure to the aquatic environment, it is not necessary to submit further studies on the effects of carbon dioxide on the reproduction and growth rate of fish (the data requirements detailed in Document III-A, 7.4.3.2).

3. Due to the fact that there is no exposure to the aquatic environment, coupled with the fact that there is no data available which suggests that carbon dioxide will bioaccumulate in the environment, nor is there a risk of secondary poisoning through the use of carbon dioxide, it is not necessary to submit data on bioaccumulation in fish (the data requirements detailed in Document III-A 7.4.3.3.1).