Section A1 **Applicant**
Annex Point IIA1

		Official use only
1.1 Applicant	[redacted] Address: Rentokil Initial plc, Felcourt, East Grinstead, West Sussex RH19 2JY United Kingdom Telephone: +44 (0)1342 833022 Fax number: +44 (0) 1342 830362 [redacted]	
1.2 Manufacturer of Active Substance (if different)	Manufacturer of carbon dioxide is as above. [redacted]	
1.3 Manufacturer of Product(s) (if different)	[redacted] [redacted] [redacted]	

Already submitted for carbon dioxide dossier for Product Type 14.

Section A2 Annex Point IIA II — **Identity of Active Substance**

Subsection (Annex Point)		Official use only
2.1 Common name (Annex IIA2.1)	This active substance is not listed in Annex I to Directive 67/548/EEC. EINECS Name: carbon dioxide. Synonyms: carbonic acid gas, carbonic anhydride.	
2.2 Chemical name (IIA2.2)	IUPAC Name: carbon dioxide	
2.3 Manufacturer's development code number(s) (IIA2.3)	Manufacturer's development code number is not applicable, as carbon dioxide is a naturally occurring gas.	
2.4 CAS no. and EC numbers (IIA2.4)		
2.4.1 CAS No.	124-38-9	
2.4.2 EC-No	204-696-9	
2.4.3 Other	None known.	
2.5 Molecular and structural formula, molecular mass (IIA2.5)		
2.5.1 Molecular formula	CO2	
2.5.2 Structural formula	O=C=O (smiles code)	
2.5.3 Molecular mass	44.01 g/mol	
2.6 Method of manufacture of the active substance (IIA2.1)	[redacted]	
2.7 Specification of the purity of the active substance, as appropriate (IIA2.7)	[redacted]	
2.8 Identity of impurities and additives, as appropriate (IIA2.8)	[redacted] [redacted] [redacted]	
2.8.1 Isomeric composition	[redacted]	

Section A2 **Identity of Active Substance**
Annex Point IIA II

2.9 The origin of the natural active substance or the precursor(s) of the active substance. (IIA2.9)	[redacted]	

Section A2 **Identity of Active Substance**
Annex Point IIA II

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Section A2 **Identity of Active Substance**
Annex Point IIA II

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 A2.10
Annex Point IIA, II, 2.10

Exposure data in conformity with Annex IIA to Council Directive 92/32/EEC (OJ No. L 05.06.1992 p.1) amending Council Directive 67/548/EEC

Official use only

2.10 Human exposure towards active substance

2.10.1.1 Production

i) Description of process

[redacted]

ii) Workplace description

[redacted]

iii) Inhalation exposure

[redacted]

[redacted]

iv) Dermal exposure

[redacted]

2.10.1.2 Intended uses

1. Professional users

i) Description of application process

Rentokil have already outlined its intended use of carbon dioxide as PT14 (rodenticides).

Rentokil also intend to use carbon dioxide under PT18 – as an insecticide fumigant.

Carbon dioxide gas is delivered into an air-tight enclosure, a fumigation bubble made from PVC coated aluminium (either prefabricated into specified dimensions) or supplied as separate sheets. Both types will be heat-sealed once the commodities to be treated have been installed within. A minimum concentration of 60% v/v carbon dioxide is achieved and maintained for a period of 3 days to 6 weeks, depending upon the temperature and target insect species.

ii) Workplace description	As a basic first introduction to this system, the following details are provided. Before a decision can be made to conduct a fumigation in any particular location, a risk assessment is carried out [redacted] [redacted] Once it has been decided that a fumigation can in fact proceed and that it is safe and practicable to do so, the following steps are followed: [redacted] 6. Carbon dioxide levels within the fumigation bubble are monitored at the beginning of the fumigation and periodically during the treatment process with levels being monitored in the surrounding area throughout. 7. Following the treatment period, carbon dioxide is pumped out of the fumigation bubble direct to the outside atmosphere and once levels have reached a suitable level, below the workplace exposure limit of 0.5%, the bubble is dismantled and contents removed. It should be noted that only highly trained individuals within Rentokil Pest Control are authorised to conduct insecticide fumigation work.

Section A2.10
Annex Point IIA, II, 2.10

Exposure data in conformity with Annex IIA to Council Directive 92/32/EEC (OJ No. L 05.06.1992 p.1) amending Council Directive 67/548/EEC

iii) Inhalation exposure	Under normal circumstances, there should be no exposure to levels of carbon dioxide above the Workplace Exposure Limit of 5000 pppm (0.5%). Should however this level be exceeded, an alarm system, set in place for every fumigation treatment will sound when levels above 0.5% are detected. In these instances, self-contained breathing apparatus is used until acceptable safe working levels (ie below 0.5%) have been attained.
iv) Dermal exposure	Carbon dioxide is a gas. The principle route of exposure is via inhalation. Exposure via the dermal route is effectively nil.
2. Non-professional users including the general public	
i) via inhalational contact	Carbon dioxide is intended for use as an insecticide, for use only by fully trained professional users. As such, primary exposure to carbon dioxide to non-professional users e.g. the general public is not applicable for the exposure assessment. Any non-operatives are excluded from the vicinity of a fumigation site until after the fumigation has been completed and a "gas clearance certificate" has been issued by the fumigator in charge. A gas clearance certificate is only issued once carbon dioxide levels have fallen below 0.1%. This figure is below the long-term Workplace Exposure Limit of 0.5%.
ii) via skin contact	Carbon dioxide is a gas. The principle route of exposure is via inhalation. Exposure via the dermal route is effectively nil. It should be noted that non-professional users (eg the general public) are excluded from any treatment sites and so should not be exposed.
iii) via drinking water	As an insecticide, carbon dioxide is intended for use in a fully self-contained fumigation bubbles. Such fumigations will always take place indoors and as such exposure to drinking water is not expected. It should be noted that non-professional users (eg the general public) are excluded from any treatment sites and so should not be exposed.
iv) via food	Certain food stuffs such as cereal grains, coffee beans, cheese, flour, cocoa powder etc may be fumigated with carbon dioxide. Carbon dioxide is a known food additive and is generally regarded as safe (GRAS). Once a fumigation is over, there is no residual gas present and as such exposure via food stuffs is not of concern. It should be noted that non-professional users (eg the general public) are excluded from any treatment sites and so should not be exposed.

Section A2.10
Annex Point IIA, II, 2.10

Exposure data in conformity with Annex IIA to Council Directive 92/32/EEC (OJ No. L 05.06.1992 p.1) amending Council Directive 67/548/EEC

v) indirect via the environment	The normal working practices of carbon dioxide as an insecticide fumigant are within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected. After treatment, carbon dioxide is vented directly to atmosphere for dispersion. It should be noted that non-professional users (eg the general public) are excluded from any treatment sites and so should not be exposed.	
2.10.2 Environmental exposure towards the active substance		
2.10.2.1 Production		
(i) Releases into water	Carbon dioxide is a gas. This means that the principle environmental compartment at risk is the atmosphere. There will be no release to watercourses. For full details refer to Reference 2.10/01 Manufacture of carbon dioxide.	
(ii) Releases into air	Refer to Reference 2.10/01- Manufacture of carbon dioxide, for details of the levels of carbon dioxide exposure to the atmosphere during its manufacture.	
(iii) Waste disposal	Carbon dioxide is a gas. Therefore any waste material will be vented to atmosphere. Refer to Reference 2.10/01- Manufacture of carbon dioxide, for details of the levels of carbon dioxide exposure to the atmosphere during its manufacture.	
2.10.2.2 Intended use(s)		
Affected compartment(s):	The normal working practices of carbon dioxide as an insecticide fumigant are within a sealed enclosure (fumigation bubble) and therefore additional exposure to the gas is not expected. After treatment, carbon dioxide is vented directly to atmosphere for dispersion. Exposure to other environmental compartments are not expected due to the intrinsic properties of carbon dioxide and its methods of use as an insecticide fumigant within a sealed enclosure (fumigation bubble).	
Predicted concentration in the environmental compartment(s):	The use of carbon dioxide as a fumigant insecticide is not expected to unduly raise concentrations within the air compartment and within both the aquatic and terrestrial compartments, levels will not increase.	

Section A2.10
Annex Point IIA, II, 2.10

Exposure data in conformity with Annex IIA to Council Directive 92/32/EEC (OJ No. L 05.06.1992 p.1) amending Council Directive 67/548/EEC

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.*
Conclusion	*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.)*
Remarks	
	COMMENTS FROM .....
Date	*Give date of comments submitted.*
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 A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Melting point, boiling point, relative density (IIA3.1)	--	--	--	--	--	--	--	
3.1.1 Melting point	Not reported – refer to remarks / justification.	See footnote (below)	- 78.5°C (sublimation temperature)	See footnote (below)	N	[redacted]	[redacted]	

Footnotes

[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1.2 Boiling point	N/A – refer to remarks / justification.	N/A – refer to remarks / justification.	N/A – refer to remarks / justification.	Boiling point is defined as the temperature at which the vapour pressure of a liquid is 101,325 Pa (normal atmospheric pressure). Carbon dioxide does not exist as a liquid at normal atmospheric pressure. It is technically not feasible to determine the boiling point of a gas. There is no approved guideline for testing the boiling point of a gas. It is also scientifically unjustified to determine the boiling point of a gas for two reasons. 1. If the test conditions were manipulated (e.g. temperature and pressure), the boiling point could not be determined because of the sublimation properties of carbon dioxide (refer to Document IIIA, section 3.1.1 for further details). 2. Carbon dioxide is a gas under the normal physical conditions it will be used in as a biocide, so determining the boiling point (even if it was possible) will not provide any useful information for the risk assessment.	N/A	0 : Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. This is because the study to determine the boiling point of carbon dioxide is technically not possible to perform. This study is also not scientifically necessary.	[redacted] [redacted]	

Subsection (Annex point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.1.3 Bulk density/ relative density	Not reported – refer to remarks / justification.	See footnote (below)	Relative density: 1.527	See footnote (below)	N	[redacted]	[redacted]	

Footnotes

[redacted]

Already submitted for carbon dioxide dossier for Product Type 14

Section A3	Physical and Chemical Properties of Active Substance

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.2 Vapour pressure (IIA 3.2)	N/A - Refer to remarks / justification	N/A - Refer to remarks / justification	N/A - Refer to remarks / justification	Vapour pressure is defined as the pressure exerted by a vapour above a liquid. This definition means that vapour pressure data is not relevant for carbon dioxide because it is a gas under the physical conditions in which it is being used as a biocide. There is no approved guideline for determining the vapour pressure of a gas. It is also scientifically unjustified, given that carbon dioxide is a gas under the normal physical conditions in which it will be used as a biocide. Determining the vapour pressure of carbon dioxide (e.g. by manipulating the test conditions e.g. temperature and pressure), will not provide any useful information for the risk assessment.	N/A	0 : Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. This is because the study to determine the vapour pressure is technically not possible to perform. This study is also not scientifically necessary.	[redacted]	

Already submitted for carbon dioxide dossier for Product Type 14

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.2.1 Henry's Law Constant (Pt. 1-A3.2)	N/A - Refer to remarks / justification	N/A - Refer to remarks / justification	N/A - Refer to remarks / justification	The Technical Guidance Document in Support of the Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products (dated October 2000), states that Henry's Law Constant expresses the tendency for a substance to evaporate from aqueous solutions. This definition means that Henry's Law Constant is not relevant for carbon dioxide because it is a gas under the physical conditions in which it is being used as a biocide. Determining the Henry's Law constant of carbon dioxide (e.g. by manipulating the test conditions such as temperature and pressure), will not provide any useful information for the risk assessment.	N/A	0 : Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. This is because the study to determine Henry's Law Constant is technically not possible to perform. This study is also not scientifically necessary.	None.	

Already submitted for carbon dioxide dossier for Product Type 14

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex point)	Method	Purity/ Specification	Results Give also data on test pressure, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.3 Appearance (IIA3.3)								
3.3.1 Physical state	Gaseous.						[redacted]	

3.3.2 Colour	Colourless.	[redacted]	
3.3.3 Odour	Odourless.	[redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex Point)	Method	Purity / Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.4 **Absorption spectra (IIA, III, 3.4)** **UV/VIS**	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex Point)	Method	Purity / Specification	Results	Remarks/ justification	GLP (Y/N)	Reliability	Reference	Official use only
3.4 Absorption spectra (IIA, III, 3.4) **IR**	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

[redacted]

Section A3 Physical and Chemical Properties of Active Substance

[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ justification	GLP (Y/N)	Reliability	Reference	Official Use only
3.4 Absorption Spectra (IIA, III, 3.4) NMR	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ justification	GLP (Y/N)	Reliability	Reference	Official Use only
3.4 **Absorption Spectra (IIA, III, 3.4)** **MS**	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

[redacted]

Already submitted for carbon dioxide dossier for Product Type 14

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.5 Solubility in water (IIA3.5) [redacted] [redacted] [redacted]	Not reported – refer to remarks / justification.	See footnote (on next page)	Carbon dioxide is sparingly soluble in water. [redacted] 0.17% at 20°C [redacted] [redacted] [redacted]	[redacted]	[redacted]	0: Not applicable. [redacted]	[redacted] [redacted]	

				[redacted]						

Effects of pH on water solubility	The document entitled "Solubility of Carbon Dioxide in Water" shows that the dissolution of carbon dioxide in water results in the formation of carbonic acid, which dissociates to produce bicarbonate and carbonate ions, and hydrogen ions. All the dissolution and dissociation reactions are at equilibrium, so if there is any change to one of the ionic species in the equilibria, the equilibrium positions change to negate the effect of the change on that species (Le Chatelier's principle). The effect of changing the pH of the water would be: 1) Lowering the pH This would increase the number of hydrogen ions in the solution. The equilibrium position would change, so that the number of dissociated hydrogen ions is reduced by recombination with the carbonate and bicarbonte ions, thus forming more carbonic acid. This increase in carbonic acid concentration would result in the equilibrium position for the formation of this species to change to produce more carbon dioxide and water. Hence the solubility of carbon dioxide at lower pH would be expected to be lower than at pH 7. 2) Increasing the pH This would decrease the number of hydrogen ions in the solution. The equilibrium position would change, so that the number of dissociated hydrogen ions is increased by dissociation of more carbonic acid molecules forming both bicarbonate and carbonate ions. The lowering of the concentration of carbonic acid would then result in the equilibrium position for the formation of carbonic acid from carbon dioxide and water to change to produce more carbonic acid. This would cause more carbon dioxide to be dissolved in the water. Hence the solubility of carbon dioxide at higher pH would be expected to be greater than at pH 7.

Footnotes

[redacted]

Section A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.6 Dissociation constant (-)	N/A -Refer to remarks/ justification	N/A -Refer to remarks/ justification	N/A -Refer to remarks/ justification	See footnote (below).	N/A	0 : Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. This is because the study to determine the dissociation constant of carbon dioxide is technically not possible to perform.	[redacted]	

Footnotes

Remarks/ Justification
Carbon dioxide is a gas under the conditions it will be marketed as a biocide. It is not technically feasible to determine the dissociation constant for a gas. There is no approved guideline for testing the dissociation constant of a gas.

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official Use only
3.7 **Solubility in organic solvents, including the effect of temperature on solubility (IIIA, III, 1)** **1 of 3 results.**	Refer to table on page two (below), for details of method.	[redacted]	Results presented in terms of the Ostwald coefficient L = V_2 / V_1 where: V_2 is the volume of gas absorbed by the volume V_1 of solvent (all measured at the same temperature). 24.56°C L = 1.84 24.62°C L = 1.86 25.02°C L = 1.89 25.07°C L = 1.87 These results show that carbon dioxide is soluble in isobutanol, and the solubility stays approximately constant between 24.5°C to 25.1°C. Note that it is not possible to express the solubility of carbon dioxide in isobutanol in cm^3 /L. This is because the amount of gas dissolved was not measured; all that was measured was the expansion of the solvent once it was saturated with gas.	[redacted]	N	2	[redacted]	

				carbon dioxide.				

Subsection (Annex Point)	Method	Official Use only
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA, III, 1) **1 of 3 results.**	1. Solubility of carbon dioxide in isobutanol. The basis of the method is attainment of equilibrium between the gas and the solvent by allowing the solvent to drip and flow through a known volume of gas. The apparatus was housed in an air thermostat, in order achieve uniform temperature. Temperature control was effected using a Hallikainen Thermodyne proportional controller, and the temperature was measured to +/- 0.003°C with a platinum resistance thermometer calibrated at the triple point of water and at the benzoic acid point. The procedure consisted of two parts: 1) Degassing. The principle of degassing involves the use of an all-gas circulating pump to continually spray the solvent into an evacuated chamber. Provisions for heating, stirring and monitoring of the pressure are incorporated. After degassing, the solvent is transferred without any contact with the atmosphere into a storage spiral inside the air thermostat. 2) Solubility determination. The degassed solvent was allowed to stand in the storage spiral for a minimum period of 2h (in practice, usually overnight) to reach the temperature of the thermostat. The apparatus is then filled with the gas under study to a pressure of just less than 1 atm. The solvent is allowed to drip into the absorption spiral until the 10 ml burets are filled to around one third of their capacity. The solvent flow is stopped and the drainage timed. From 30-60 minutes after the end of the first solvent flow, levels of the solvent in the 10 ml burets and the mercury in the 50 ml buret are measured with a cathometer. The pressure is adjusted to atmospheric and fixed by closing the tap in the external limb of the silicon oil manometer. Solvent is allowed to drip into the apparatus at a rate previously determined to be in the range where complete saturation occurs. The levels in the silicon oil manometer and the 10 ml burets are kept as nearly equal as possible during the process of solution so that the pressure remains close to the original atmospheric pressure. Excess solvent is run from the apparatus through the stopcock at approximately the input rate. The solvent is collected in a tared flask. After a sufficient volume of gas has been dissolved, the flow is stopped. The pressure throughout the apparatus is adjusted to the initial value and the levels in the 10 ml burets and the 50 ml buret are measured. From these observations and the weight and density of the solvent, the solubility of the gas can be measured.	

[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex Point)		Method	Purity/ Specification	Results	Remarks/ justification	GLP (Y/N)	Reliability	Reference	Official Use only
3.7	**Solubility in organic solvents, including the effect of temperature on solubility (IIIA, III, 1)** **2 of 3 results.**	<u>1.. Solubility in cyclohexanol</u> Cyclohexanol was purified via the process of distillation. Two "Baudin" test tubes graduated with 1/20cm³ were used. One contained cyclohexanol and the other CO_2. The CO_2 was added to the test tube containing cyclohexanol, and agitated. The volume of remaining gas and total volume is measured, thereby determining solubility.	[redacted]	677 cm³ CO_2/litre cyclohexanol (at 26°C pressure 766 mmHg).	[redacted]	N	2	[redacted]	

[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ justification	GLP (Y/N)	Reliability	Reference	Official Use only
3.7 **Solubility in organic solvents, including the effect of temperature on solubility (IIIA, III, 1)** **3 of 3 results.**	1. Solubility in γ-butyrolactone, ε-caprolactone, propylene carbonate, ethylene carbonate, dimethylcarbonate, diethylcarbonate. Refer to table on page two (below), for details of method.	[redacted]	Refer to table on page three (below) for details.	[redacted]	N	2	[redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ justification	GLP (Y/N)	Reliability	Reference	Official Use only
							[redacted] [redacted] [redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ justification	GLP (Y/N)	Reliability	Reference	Official Use only
							[redacted]	

[redacted]

Subsection (Annex Point)	Method	Official Use only
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA, III, 1) **3 of 3 results.**	1. Solubility in γ-butyrolactone, ε-caprolactone, propylene carbonate, ethylene carbonate, dimethylcarbonate, diethylcarbonate. In order to determine the Henry's law constant of carbon dioxide in each solvent, the solvent was previously saturated with carbon dioxide at atmospheric pressure. Dissolved carbon dioxide was displaced by an argon flow and trapped in a vessel containing a sodium hydroxide solution of known concentration. The solvent's vapours are liquefied in a cooled methanol bath. When all the carbon dioxide had been removed from the tested solution, the sodium hydroxide solution was titrated by a standard hydrochloric acid solution. Each measurement was run in triplicate.	

Subsection (Annex Point)	Results	Official Use only
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA, III, 1) **3 of 3 results.**	Henry's Law constant (Atm) for carbon dioxide in each solvent at different temperatures	

T °C	EC	DMC	PC	DEC	CL	BL
2	Solid	Solid	52.6	40.0	65.4	70.9
10	Solid	53.4	---	---	---	---
18	158.7*	60.9	81.8	53.2	86.9	97.2
40	202.0	---	---	---	---	---
43	---	108.1	128.9	78.9	---	162.8
60	271.5	---	---	---	---	---

Key

T°C	Temperature in °C
EC	Ethylene carbonate
DMC	Dimethylcarbonate
PC	Propylene carbonate
DEC	Diethylcarbonate
CL .	ε-caprolactone
BL	γ-butyrolactone
*	Figure extrapolated from measurements taken in PC/EC and DMC/EC mixtures, because ethylene carbonate is not a liquid at room temperature.

Discussion

Not including above, two other pieces of data have been submitted in the dossier which consider the solubility of carbon dioxide in organic solvents. However, these pieces of data do not consider the effect of temperature on solubility. The information given here does not give the exact volume of carbon dioxide that is soluble in the solvent nor is it in conventional units of cm^3/L or % v/v. However it is intended to demonstrate the effect of temperature on the solubility of carbon dioxide in organic solvents.

Henry's Law states that the concentration of a solute gas in a solution is directly proportional to the partial pressure of that gas above the solution. The value of the Henry's Law constant is found to be temperature dependant. The value generally increases with increasing temperature. As a consequence, the solubility of gases generally decreases with increasing temperature. The values given above, although not in conventional units of cm^3/L or % v/v show that carbon dioxide solubility in ethylene carbonate, dimethylcarbonate, diethylcarbonate, ε-caprolactone and γ-butyrolactone decreases with increasing temperature (as demonstrated by

Section A3 Physical and Chemical Properties of Active Substance

	the fact that the value for Henry's Law constant increases as the temperature rises).	

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products. (IIIA3.2)	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	The Technical Guidance Document in Support of the Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products (dated October 2000) states that stability in organic solvents must only be determined if the active ingredient, as manufactured, includes an organic solvent. Carbon dioxide [redacted] does not contain any organic solvents, therefore stability data for carbon dioxide in organic solvents is not required.	N/A	0: Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. This is because the study to determine the stability of carbon dioxide in organic solvents is not scientifically necessary.	None.	

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official Use only
3.9 **Partition coefficient n-octanol/water (IIA, III, 3.6)** **(1 of 2 values)**	Not given. - Refer to remarks/ justification.	Not given. *See footnote for remarks/ justification	Partition Coefficient *K* for carbon dioxide at about 25°C: Isobutanol and water: 2.26 Olive oil and water: 1.74	[redacted]	N	3	[redacted]	

[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official Use only
3.9 Partition coefficient n-octanol/water (IIA, III, 3.6) **(2 of 2 values)** *Nb. Refer to pages 2 and 3 for information on the effect of temperature and pH on partition coefficient.*	N/A – calculated partition coefficient.	N/A – calculated partition coefficient. *See footnote for remarks/ justification	Log pow: 0.83	[redacted]	N	3	[redacted]	

[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Effect of temperature and pH on partition coefficient	Official Use only
3.9 **Partition coefficient n-octanol/water (IIA, III, 3.6)**	[redacted] It is acknowledged that pH and temperature will effect the partition coefficient of carbon dioxide. Indeed, the data given in Document IIIA section 3.5 water solubility and Document IIIA section 3.7 solubility in organic solvents shows that the solubility of carbon dioxide in water is effected by pH and temperature, and solubility in organic solvents is effected by temperature. Predicting the effect of changes in temperature and pH on the partition coefficient of carbon dioxide is very complex and needs to take into account thermodynamics, reaction equilibria and kinetics. Because the solubility values of carbon dioxide are so low, any errors in the theoretical assumption could radically change the outcome. A study to experimentally determine the effect of pH and temperature on the partition coefficient of carbon dioxide has not been considered necessary because: The partition coefficient values available for carbon dioxide (and cited in the dossier), despite not considering the effect of pH and temperature, suggests that carbon dioxide has a very low bioconcentration potential (Log Pow values are less than 3.0).[2] Data available on the effect of temperature on partition coefficient values suggests in general terms that the effect of temperature on kow values are not dramatic (usually the order of 0.001 to 0.01 log kow units per degree in temperature – may be positive or negative)[1]. If the same can be assumed to be true about the effect of pH, then no useful additional information will be gained from determining the effect of temperature and pH on the partition coefficient of carbon dioxide – the conclusion about it having a low bioaccumulation potential will be unchanged.	

References:

[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.10 Thermal stability, identity of relevant breakdown products (IIA, 3.7)	Not reported – refer to remarks/ justification.	[redacted]	A thermodynamic study has determined the thermal decomposition products of carbon dioxide by calculating the equilibrium concentrations of the decomposition products as a function of temperature and total pressure. It was found that over a fairly wide range of temperature and pressure, carbon dioxide dissociates into carbon monoxide and oxygen with no precipitation of carbon. For example, the temperature range is 250-370°C at 0.02 atm, 320-480°C at 1 atm and 405-630°C at 100 atm. At higher temperatures in each case, carbon is also formed but always in the presence of some oxygen. $CO2 \leftrightarrow CO + 1/2\ O2$	The thermal stability data provided has been sourced from data found in the public domain. Experimental determination of the thermal stability of the carbon dioxide prescribed in this application will not add any new information to the huge volume of physical chemical data available for carbon dioxide, which is in broad agreement regarding the accepted thermodynamics of carbon dioxide.	N	2 : Study conducted in accordance with generally accepted scientific principles, possibly with incomplete reporting or methodological deficiencies, which do not affect the quality of relevant results. [redacted]	[redacted] [redacted]	

Section A3 **Physical and Chemical Properties of Active Substance**

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.11 Flammability, including auto-flammability and identity of combustion products. (IIA, 3.8)	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	A test to determine the flammability and auto-ignition temperature of carbon dioxide has not been conducted. This is because it is widely known and accepted that carbon dioxide is a non-flammable gas that does not support combustion. Indeed, carbon dioxide is used as an extinguishing agent for fires involving flammable liquids or electrical equipment. Conducting a flammability and auto flammability test for carbon dioxide will only serve to confirm this well-established property of carbon dioxide, and will not provide any new information for the risk assessment.	N/A	0: Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. It is not scientifically necessary to conduct a flammability and auto flammability test for carbon dioxide.	None.	

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.12 Flash-point (IIA3.9)	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	Flash point is defined as the lowest temperature, corrected to a pressure of 101,325 Pa (normal atmospheric pressure), at which a liquid evolves vapours, under specified test conditions, in such an amount that a flammable vapour/air mixture is produced. Carbon dioxide does not exist as a liquid at normal atmospheric pressure. It is a gas under the conditions it will be marketed as a biocide. It is technically not feasible to determine the flash point of a gas. There is no approved guideline for testing the flash point of a gas. Notwithstanding this, it is also not scientifically necessary to conduct a flash point test for carbon dioxide on the basis that it is well established and accepted that carbon dioxide is a non-flammable gas that does not support combustion.	N/A	0 : Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. This is because the study to determine the flash point of carbon dioxide is technically not possible to perform. This study is also not scientifically necessary.	[redacted]	

Section A3 **Physical and Chemical Properties of Active Substance**

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.13 Surface tension (IIA3.10)	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	The test methods described in Directive 92/69/E.E.C A.5 only apply to the measurement of surface tension of aqueous solutions. Carbon dioxide does not exist as an aqueous solution at normal atmospheric pressure. It is a gas under the conditions it will be marketed as a biocide. It is technically not feasible to determine the surface tension of a gas. There is no approved guideline for determining the surface tension of a gas. It is also scientifically unjustified, given that carbon dioxide is a gas under the normal physical conditions it will be used as a biocide. Determining the surface tension of carbon dioxide (by manipulating the test conditions e.g. temperature and pressure), will not provide any useful information for the risk assessment.	N/A	0 : Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. This is because the study to determine the surface tension of carbon dioxide is technically not possible to perform. This study is also not scientifically necessary.	[redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.14 Viscosity (-)	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	The Technical Guidance Document in Support of the Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance for Data Requirements for Active Substances and Biocidal Products, Version 4.3.2 dated October 2000 states that viscosity should be measured for liquid substances only. Carbon dioxide does not exist as a liquid at normal atmospheric pressure. It is a gas under the conditions it will be marketed as a biocide. It is technically not feasible to determine the viscosity of a gas. There is no approved guideline for testing the viscosity of a gas. It is also scientifically unjustified, given that carbon dioxide is a gas under the normal physical conditions it will be used as a biocide. Determining the viscosity of carbon dioxide (by manipulating the test conditions e.g. temperature and pressure), will not provide any useful information for the risk assessment.	N/A	0 : Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. This is because the study to determine the viscosity of carbon dioxide is technically not possible to perform. This study is also not scientifically necessary.	None.	

Section A3 **Physical and Chemical Properties of Active Substance**

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.15 Explosive properties (IIA3.11)	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	The test method Directive 92/69/E.E.C A.14 Explosive Properties states that the test for explosive properties need not be performed when available thermodynamic information (e.g. heat of formation, heat of decomposition) and/or absence of certain reactive groups in the structural formula establishes beyond reasonable doubt that the substance does not present any risk of explosion. It is widely known and accepted that carbon dioxide is thermodynamically stable and therefore does not exhibit explosive properties. Conducting an explosivity test for carbon dioxide will only serve to confirm this well-established property of carbon dioxide, and will not provide any new information for the risk assessment.	N/A	0: Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. It is not scientifically necessary to conduct an explosivity test for carbon dioxide.	[redacted]	

Section A3 **Physical and Chemical Properties of Active Substance**

Already submitted for carbon dioxide dossier for Product Type 14

Subsection (Annex point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.16 Oxidising properties (IIA3.12)	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	N/A - Refer to remarks/ justification	The test methods described in Directive 92/69/E.E.C A. 17 only applies to solid materials. Carbon dioxide is not a solid at normal atmospheric pressure. It is a gas under the conditions it will be marketed as a biocide. It is not technically possible to determine whether carbon dioxide has oxidising properties because there are no approved guidelines for testing the oxidising properties of a gas. Notwithstanding this, examination of the structural formula of carbon dioxide, along with the fact that it is widely accepted that carbon dioxide is thermodynamically stable, suggests that carbon dioxide will not exhibit oxidising properties, even if it could be tested.	N/A	0 : Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. This is because the study to determine whether carbon dioxide has oxidising properties is technically not possible to perform. This study is also not scientifically necessary.	[redacted]	

Subsection (Annex point)	Method	Purity/ Specification	Results Give also data on test pressure, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.17 Reactivity towards container material (IIA3.13)	Carbon dioxide is supplied in containers designed and manufactured in accordance with: [redacted] Containers manufactured to either specification will ensure that there is no reactivity between the carbon dioxide and its container. [redacted]							

Section A4.1
Annex Point IIA, IV, 4.1

Analytical Methods for Detection and Identification
Purity of Active Ingredient

				Official use only
		1. REFERENCE		
1.1	**Reference**	[redacted]		
1.2	**Data protection**	[redacted]		
1.2.1	Data owner	[redacted]		
1.2.2				
1.2.3	Criteria for data protection	[redacted]		
		2.		
2.1				
2.2				
2.3				
		3. MATERIALS AND METHODS		
3.1	**Preliminary Treatment**			
3.1.1.	Enrichment	Not applicable.		
3.1.2	Cleanup	Not applicable.		
3.2	**Detection**			
3.2.1	Separation method	Infrared Analysis:	Not applicable.	
		Asco Method:	A known volume of test gas is isolated in a gas burette and treated with Potassium Hydroxide solution.	
3.2.2	Detector	Infrared Analysis:	SICK MAIHAK UNOR S710 Infrared Analyser.	
		Asco Method:	Asco Carbon Dioxide Gas Purity Tester.	
3.2.3	Standards	Infrared Analysis:	95.21 % carbon dioxide gas (balance: N_2)	
		Asco Method:	Standard gas not necessary.	
3.2.4	Interfering substances	None. However, note that residual gases in the carbon dioxide are measured by the Asco method.		
3.3	**Linearity**			
3.3.1	Calibration range	Infrared Analysis:	The procedure described is suitable for concentrations within the range of 99-100% carbon dioxide.	
		Asco Method:	The method described is suitable for measuring the concentration of residual gases in carbon dioxide in the range 50-1000 ppm v/v (0.005% v/v to 1.000 % v/v) in graduations of 50 ppm v/v.	

3.3.2	Number of measurements	Infrared Analysis:	4 samples of carbon dioxide, each analysed 5 times.
		Asco Method:	3 samples of carbon dioxide, each analysed 5 times.

3.3.3	Linearity	Infrared Analysis: Asco Method:	$r^2 = 0.9912$ $r^2 = 0.9999$
3.4	**Specifity: interferring substances**	None. However, note that residual gases in the carbon dioxide are measured by the Asco method.	
3.5	**Recovery rates at different levels**	Not reported.	
3.5.1	Relative standard deviation	Not reported.	
3.6	**Limit of determination**	Infrared Analysis:	The procedure described is suitable for concentrations within the range of 99-100% carbon dioxide.
		Asco Method:	The method described is suitable for measuring the concentration of residual gases in carbon dioxide in the range 50-1000 ppm v/v (0.005% v/v to 1.000 % v/v) in graduations of 50 ppm v/v.
3.7	**Precision**		
3.7.1	Repeatability	<u>Infrared Analysis:</u>	
		0.118% N_2 in CO_2:	100.03% 100.04 % 100.03 % 100.04 % 100.03 %
		0.327 % N_2 in CO_2:	99.83 % 99.83 % 99.82 % 99.82 % 99.82 %
		0.522 % N_2 in CO_2:	99.50 % 99.49 % 99.49 % 99.49 % 99.49%
		1.01 % N_2 in CO_2:	99.0 % 98.99 % 98.99 % 98.99 % 98.99 %
		<u>Asco method:</u>	
		0.118% N_2 in CO_2:	0.16% 0.16 % 0.16 % 0.16 % 0.16 %
		0.327% N_2 in CO_2:	0.36 % 0.36 % 0.36 % 0.36 % 0.36%

		$0.522\%\ N_2$ in CO_2: 0.54 % 0.54 % 0.54 % 0.54 % 0.54%

3.7.2 Independent laboratory validation

Method validated by a second operator in the same laboratory. Results are as follows:

Infrared Analysis:

$0.118\%\ N_2$ in CO_2:	100.05% 100.04 % 100.04 % 100.04 % 100.04 %
$0.327\ \%\ N_2$ in CO_2:	99.83 % 99.83 % 99.83 % 99.82 % 99.83 %
$0.522\ \%\ N_2$ in CO_2:	99.50 % 99.49 % 99.49 % 99.50 % 99.49%
$1.01\ \%\ N_2$ in CO_2:	99.00 % 98.99 % 98.99 % 98.99 % 98.99 %

Asco method:

$0.118\%\ N_2$ in CO_2:	Operator 1:	0.16 %
	Operator 2:	0.15 %
$0.327\%\ N_2$ in CO_2:	Operator 1:	0.36 %
	Operator 2:	0.37 %
$0.522\%\ N_2$ in CO_2:	Operator 1:	0.54 %
	Operator 2:	0.55 %

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Infrared Analysis:

The infrared analyser measures the total carbon dioxide level of the test gas in respect to a zero gas, which is 100% carbon dioxide in this method. The Infrared analyser is "zeroed" using a zero gas of 100% carbon dioxide, and then test gases are analysed.

Asco method:

A known volume of test gas is isolated in a gas burette and treated with Potassium Hydroxide solution. The carbon dioxide dissolves leaving a bubble of residual gases which are left in the measuring section of the burette, where its volume is read off.

4.2 Conclusion

The infrared and Asco results are fairly consistent between different analysts. The linearity regression (R^2) is very close to one for both procedures, which indicates that the variability of the response of the instruments/procedures is low. There is good correlation between the actual result and certified concentration limits as specified on the calibration mixes.

		Infrared uncertainty: 0.031 Asco uncertainty: 0.02	
4.2.1	Reliability	1	
4.2.2	Deficiencies	None.	

Section A4.1 **Analytical Methods for Detection and Identification**

Annex Point IIA, IV, 4.1 Purity of Active Ingredient

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

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

Section 4.2 **Annex Point IIA, IV 4.2**	**Analytical Methods for Detection and Identification in Environmental Media: Soil**	
	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** **[4]**	
Detailed justification:	When used as a biocide within its totally enclosed system, carbon dioxide does not enter the soil compartment because there is no mechanism for it to be released directly into the soil. This means that the use of carbon dioxide, when used as a biocide, does not affect levels of carbon dioxide found in the environment, outside normal atmospheric levels. It is for these reasons that an analytical method for detection of carbon dioxide in soil has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*
Remarks	
	COMMENTS 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 4.2 **Annex Point IIA, IV 4.2**	**Analytical Methods for Detection and Identification in Environmental Media: Air** Already submitted for carbon dioxide dossier for Product Type 14.	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [4]	
Detailed justification:	Given that carbon dioxide is a gas, the analytical method specified in Document IIIA, Section 4.1 is suitable for detecting carbon dioxide in air.	
Undertaking of intended data submission [ ]	Not applicable	

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

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

Section 4.2 **Annex Point IIA, IV 4.2**	**Analytical Methods for Detection and Identification in Environmental Media: Water**	
	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** [4]	
Detailed justification:	When used as a biocide within its totally enclosed system, carbon dioxide does not enter the aquatic compartment because there is no mechanism for it to be released directly into water. This means that the use of carbon dioxide, when used as a biocide, does not affect levels of carbon dioxide found in the environment, outside normal atmospheric levels. It is for these reasons that an analytical method for detection of carbon dioxide in water has not been submitted.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATES *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

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

Already submitted for carbon dioxide dossier for Product Type 14.

Section 4.2 **Annex Point IIA, IV 4.2**	**Analytical Methods for Detection and Identification in Environmental Media: Animal and Human Body Fluids and Tissues** Already submitted for carbon dioxide dossier for Product Type 14.	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [4]	
Detailed justification:	The Technical Guidance Document in Support of the Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance for Data Requirements for Active Substances and Biocidal Products, Version 4.3.2 dated October 2000 states that an analytical method for detection of residues in animal and human body fluids and tissues is only required when the active substance is classified as toxic or highly toxic. Carbon dioxide is not classified as hazardous according to EC Directive 67/548/EEC, and therefore it is not necessary to submit an analytical method to detect carbon dioxide residues in animal and human body fluid and tissues. In addition, for blood the following applies: Following discussions with the Public Analyst in the UK, a method of analysis for CO2 in blood is not considered relevant. Any measurement of CO2 levels in blood (to give a meaningful result) would have to be carried out either in vivo or immediately after drawing the blood. Any CO2 present in the blood will diffuse out and be metabolised and will either not be detectable or present at a reduced level soon after sampling. Further enquiries made through the UK National Poisons Information Centre, again confirmed that such measurements would not prove to be of direct relevance or indeed practicality. But the following details can be provided on methods used : In the UK there are three different types of methods that can be used (within medical facilities) for measuring levels of CO_2 in blood. 1. PET CO_2 – this is the pressure of the end tidal flow of CO_2. It is measured from expired breath and then a calculation is carried out to extrapolate the levels found in the breath to levels within the blood. 2. PA CO_2 – this is the pressure of arterial CO_2. It is a direct blood measurement and used in intensive care facilities within hospitals and in medical research. It is based upon spectrometer readings.	

Section 4.2 **Annex Point IIA, IV 4.2**	**Analytical Methods for Detection and Identification in Environmental Media: Animal and Human Body Fluids and Tissues** **Already submitted for carbon dioxide dossier for Product Type 14.**
	3. PTC CO_2 – there are two methods relating to the pressure of transcutaneous CO_2. The first is an old method based upon spetrophotometric analysis of blood (looking at colour changes in the blood). The second uses specialist proprietary electrodes. This is a more commonly used method and readings are calibrated against a mass spectrometer.
Undertaking of intended data submission [ ]	Not applicable

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

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

Section 4.3 Annex Point IIIA, IV 1	Analytical methods, including recovery rates and the limits of determination for residues in/on food or feedstuffs and other products where relevant	
	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** [4]	
Detailed justification:	The Technical Guidance Document in Support of the Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance for Data Requirements for Active Substances and Biocidal Products, Version 4.3.2 dated October 2000 states that analytical methods for the determination of the active substance, and for residues thereof, in/on food or feeding stuffs and other products should only be submitted if the active substance (or the material treated with it) is to be used in a manner such that it would come into contact with food or feeding stuffs, or will be used in soils which are intended for agriculture or horticultural use. Carbon dioxide, either as an active ingredient or a biocidal product is not intended for use on agricultural or horticultural soil. Carbon dioxide fumigations are carried out on certain foodstuffs and it should be noted that carbon dioxide is generally recognised as a safe food substance (GRAS). In 1981, the Environmental Protection Agency in the USA waived the need for data requirements pertaining to toxicological studies, metabolism studies, analytical methods and residue data. The final ruling was given as follows: The food additive carbon dioxide may be safely used after harvest in modified atmospheres for stored product insect control on all processed agricultural commodities. As such, it is not necessary to submit an analytical method for the determination of carbon dioxide in / on food or feeding stuffs or other products. [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	

Subsection (Annex Point)		Official use only
5.1 Function (IIA5.1)	**INSECTICIDE**	
5.2 Organism(s) to be controlled and products, organisms or objects to be protected. (IIA5.2)		
5.2.1 Organism(s) to be controlled (IIA5.2)	The pest organisms to be controlled include the following insect orders: Dictyoptera (cockroaches), Coleoptera (beetles), Lepidoptera (butterflies and moths), Psocoptera (booklice) , Acari (mites) and Hempitera (bugs). Examples of the species to be controlled include the following:	

Acarus siro	Flour mite
Anastrephus suspensa	Caribbean fruit fly
Anobium punctatum	Common furniture beetle
Anthrenus verbasci	Varied carpet beetle
Blatella germanica	German cockroach
Callosobruchus chinensis	Cowpea weevil
Cimex lectularius	Bed bug
Dermestes maculatus	Leather beetle
Ephestia cautella	Tropical warehouse moth
Ephestia keuhniella	Mediterranean flour moth
Lasioderma serricorne	Cigarette beetle
Lepinotus patruelis	Booklouse
Liposcelis bostrychophilus	Booklouse
Oryzaephilus mercator	Merchant grain beetle
Oryzaephilus surinamensis	Saw-toothed grain beetle
Periplaneta americana	American cockroach
Plodia interpunctella	Indian-meal moth
Ptinus tectus	Australian spider beetle
Sitophilus granarium	Grain weevil
Sitophilus oryzae	Rice weevil
Sitotroga cerealella	Angoumois grain moth
Tribolium castaneum	Rust red flour beetle
Tribolium confusum	Confused flour beetle
Trogoderma glabrum	Warehouse beetle
Trogoderma granarium	Khapra beetle
Tyrophagus putrescentiae	Mould mite

Section A5		Effectiveness against target organisms and intended uses	
5.2.2	**Products, organisms or objects to be protected. (IIA5.2)**	Carbon dioxide can be used as a biocide in public hygiene situations for the treatment of a variety of non-food products including the following: Packaging materials; Transport containers Food processing machinery; Manufactured goods Textiles; Hides Tobacco; Dried flowers Museum artefacts Carbon dioxide can also be used as a biocide in food storage practice situations for the treatment of a variety of foodstuffs such as: Cereal grains; Oilseeds Coffee beans; Flour Fishmeal; Cocoa powder Cheese; Biscuits Confectionery	
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**	See the fully referenced summary table of experimental data on the effectiveness of the active substance against target organisms.	
5.3.1	**Effects on target organism(s)**	Effects on target organisms prior to mortality are non-specific and are not well defined in the literature. Subtle physiological effects due to elevated carbon dioxide levels have been reported; increased use of oxygen (i.e. respiration), reduced fecundity and reduced life span of adults. Carbon dioxide seems to exert its anaesthetic effect directly on the nervous system via the trachea and not via the blood. In experiments with locusts and ^{14}C-labelled carbon dioxide, ^{14}C was detected in all insect body parts, but its relative persistence was highest (up to 24 hr) in the central nervous system or its immediate vicinity. Pure carbon dioxide has an inhibitory effect on the bioelectrical responses of the nervous system, while a smaller concentration (15%) has a stimulatory effect(A5.3/23). Carbon dioxide has also been reported to induce depolarisation of the neurons.	
5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**	Within a fumigation bubble, carbon dioxide levels are maintained at a minimum concentration of 60% v/v. Reference A5.3/27 supports this.	
5.4	**Mode of action (including time delay) (IIA5.4)**		

5.4.1	**Mode of action**	Most insects respire by means of a tracheal system. In this system, gas is directly transported to the tissues by air-filled tubules that bypass blood. The pores to the outside, called spiracles, deliver the gases of respiration. The drawback of this system is that the gases diffuse slowly in the long narrow tubules; as a result, these tubes need to be limited in size for adequate gas transfer. The advantage is that oxygen and carbon dioxide diffuse much faster, 10,000 times faster, from the air than in water, blood or tissues. Unlike in mammals however, there is uncertainty as to whether the actions of carbon dioxide on insects result from a specific effect of this agent, from anoxia (reduced oxygen levels), and/or pH variations. Ref A5.4/01. What is known, is that with increasing levels of carbon dioxide, narcosis will occur, followed ultimately by death. Ref A5.4/2.	
5.4.2	**Time delay**	Mortality will be achieved between 3 days and 4 weeks, depending upon insect species present.	
5.5	**Field of use envisaged (IIA5.5)**		
	MG01: Disinfectants, general biocidal products	Not applicable.	
	MG02: Preservatives	Not applicable.	
	MG03: Pest Control	Product Type 14 Product type 18	
	MG04: Other Biocidal products	Not applicable.	
	Further specification	Not required.	
5.6	**User (IIA5.6)**		
	Industrial	Carbon dioxide is not intended for industrial applications.	
	Professional	Carbon dioxide is to be used as an insecticide by professional pest control operators only.	
	General public	Carbon dioxide not intended for use as an insecticide, by the general public.	

Section 5.3: Summary Table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable.

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference *)
Insecticide	Product type 18	Carbon dioxide (specification identical to that given in section 2 of application)	*Acarus siro* Flour mite	*A. siro* was reared in a medium of plain flour and dried yeast powder in a ratio of 12:1 at 22°C and 75% RH. Approx. 5ml of live insect culture was inoculated into existing mite cultures and into a 35-litre fumigation chamber (a high-density polyethylene drum) and test conditions maintained. Mortality was assessed at the end of exposure period and again, 48 hours later.	Atmosphere = 60% CO_2: air Temperature = 35°C Relative humidity = 75% - maintained using open jars of saturated sodium chloride	100% mortality of mixed stages after 1 day exposure to modified atmosphere. <u>Mode of action:</u> Most insects respire by means of a tracheal system. In this system, gas is directly transported to the tissues by air-filled tubules that bypass blood. The pores to the outside, called spiracles, deliver the gases of respiration. The drawback of this system is that the gases diffuse slowly in the long narrow tubules; as a result, these tubes need to be limited in size for adequate gas transfer. The advantage is that oxygen and carbon dioxide diffuse much faster, 10,000 times faster, from the air than in water, blood or tissues. Unlike in mammals however, there is uncertainty as to whether the actions of carbon dioxide on insects result from a specific effect of this agent, from anoxia (reduced oxygen levels), and/or pH variations. What is known, is that with increasing levels of carbon dioxide, narcosis will occur, followed ultimately by death. <u>Resistance:</u> This test does not give any indication of resistance. In fact, resistance would not be expected with the use of carbon dioxide as an insecticide as it is lethal to the target insects in a single dose. As such, there is no mechanism for resistance to develop because target organisms are never exposed to sub-lethal concentrations of carbon dioxide (as a biocide).	A5.3/08

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference *)
Insecticide	Product type 18	Carbon dioxide (specification identical to that given in section 2 of application)	*Anastrepha suspensa* Carribean fruit fly	50 (2-3 day old) eggs were placed on laboratory agar diets in petri dishes. Three dishes were placed on wet sand in each test jar. Tests were conducted at 2 temperatures (10°C and 15.6°C) and in 9 different atmospheres for 4 exposure periods (3,5,7 and 10 days). After exposure, the dishes were held in air at 24-26° and 90% RH to allow insect development to proceed. Normally formed puparia were counted as survivors.	Atmosphere = 50%CO_2: 2%O_2 : 48% N_2 Temperature = 15°C Relative humidity = 90%	100% mortality of egg and larval stages after 7 days exposure to modified atmosphere. <u>Mode of action:</u> Most insects respire by means of a tracheal system. In this system, gas is directly transported to the tissues by air-filled tubules that bypass blood. The pores to the outside, called spiracles, deliver the gases of respiration. The drawback of this system is that the gases diffuse slowly in the long narrow tubules; as a result, these tubes need to be limited in size for adequate gas transfer. The advantage is that oxygen and carbon dioxide diffuse much faster, 10,000 times faster, from the air than in water, blood or tissues. Unlike in mammals however, there is uncertainty as to whether the actions of carbon dioxide on insects result from a specific effect of this agent, from anoxia (reduced oxygen levels), and/or pH variations. What is known, is that with increasing levels of carbon dioxide, narcosis will occur, followed ultimately by death. <u>Resistance:</u> This test does not give any indication of resistance. In fact, resistance would not be expected with the use of carbon dioxide as an insecticide as it is lethal to the target insects in a single dose. As such, there is no mechanism for resistance to develop because target organisms are never exposed to sub-lethal concentrations of carbon dioxide (as a biocide).	A5.3/09

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference *)
Insecticide	Product type 18	Carbon dioxide (specification identical to that given in section 2 of application)	*Anobium punctatum* Common furniture beetle	*A. punctatum* was reared in a hazel tree branch of 25-35mm diameter at 22°C and 75% RH. X-radiography was used to select suitable branches for placement into a 35-litre fumigation chamber (a high-density polyethylene drum) and test conditions maintained. Mortality was assessed by X-radiography at 2days and then 3 months after exposure period.	Atmosphere = 60% CO_2: 40% air Temperature = 35°C Relative humidity = 75% - maintained using open jars of saturated sodium chloride	100% mortality of larval stages after 14 days exposure to modified atmosphere. <u>Mode of action:</u> Most insects respire by means of a tracheal system. In this system, gas is directly transported to the tissues by air-filled tubules that bypass blood. The pores to the outside, called spiracles, deliver the gases of respiration. The drawback of this system is that the gases diffuse slowly in the long narrow tubules; as a result, these tubes need to be limited in size for adequate gas transfer. The advantage is that oxygen and carbon dioxide diffuse much faster, 10,000 times faster, from the air than in water, blood or tissues. Unlike in mammals however, there is uncertainty as to whether the actions of carbon dioxide on insects result from a specific effect of this agent, from anoxia (reduced oxygen levels), and/or pH variations. What is known, is that with increasing levels of carbon dioxide, narcosis will occur, followed ultimately by death. <u>Resistance:</u> This test does not give any indication of resistance. In fact, resistance would not be expected with the use of carbon dioxide as an insecticide as it is lethal to the target insects in a single dose. As such, there is no mechanism for resistance to develop because target organisms are never exposed to sub-lethal concentrations of carbon dioxide (as a biocide).	A5.3/08

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference *)
Insecticide	Product type 18	Carbon dioxide (specification identical to that given in section 2 of application)	*Anthrenus verbasci* Varied carpet beetle	Cultures of *A. verbasci* were inoculated with larvae 7-10 days before exposure in a 35-litre fumigation chamber (a high-density polyethylene drum) and test conditions maintained. Mortality was assessed at the end of exposure period and again, 48 hours later.	Atmosphere = 60% CO_2: air Temperature = 35°C Relative humidity = 75% - maintained using open jars of saturated sodium chloride	100% mortality of larval stages after 2 days exposure to modified atmosphere. Mode of action: Most insects respire by means of a tracheal system. In this system, gas is directly transported to the tissues by air-filled tubules that bypass blood. The pores to the outside, called spiracles, deliver the gases of respiration. The drawback of this system is that the gases diffuse slowly in the long narrow tubules; as a result, these tubes need to be limited in size for adequate gas transfer. The advantage is that oxygen and carbon dioxide diffuse much faster, 10,000 times faster, from the air than in water, blood or tissues. Unlike in mammals however, there is uncertainty as to whether the actions of carbon dioxide on insects result from a specific effect of this agent, from anoxia (reduced oxygen levels), and/or pH variations. What is known, is that with increasing levels of carbon dioxide, narcosis will occur, followed ultimately by death. Resistance: This test does not give any indication of resistance. In fact, resistance would not be expected with the use of carbon dioxide as an insecticide as it is lethal to the target insects in a single dose. As such, there is no mechanism for resistance to develop because target organisms are never exposed to sub-lethal concentrations of carbon dioxide (as a biocide).	A5.3/08

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference *)
Insecticide	Product type 18	Carbon dioxide (specification identical to that given in section 2 of application)	*Blatella germanica* German cockroach	Nymphal stage and adult cockroaches were placed in clear plastic petri dishes that also contained cotton and a dog food pellet. A hole was drilled in the side of each dish that would allow the use of a hypodermic syringe to moisten the cotton without removing the lid. Each dish was plugged with cotton and the edges of the hole for the syringe was lined with petroleum jelly to prevent cockroaches moving in or out of petri dish. Tests were conducted in an incubator and all temperatures were regulated to ± 0.5°C.	Atmosphere: 93.8% CO_2 <u>Exposure times:</u> Nymphal stages and adults : 3 hours Egg bearing females:0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5 & 24 hours. <u>Temperatures:</u> Nymphal stages and adults were tested at 32.2°C. Egg bearing females were tested at 16.1°C, 22.8°C, 26.7°C, 31.1°C and 33.3°C.	A 3 hour exposure at of CO_2 at 32°C to nymphal stages and adults resulted in 100% knockdown, followed by death in a few days. 100% efficacy against eggs was achieved after 6.5 hours following exposure to CO_2 at 26.7°C. <u>Mode of action:</u> Most insects respire by means of a tracheal system. In this system, gas is directly transported to the tissues by air-filled tubules that bypass blood. The pores to the outside, called spiracles, deliver the gases of respiration. The drawback of this system is that the gases diffuse slowly in the long narrow tubules; as a result, these tubes need to be limited in size for adequate gas transfer. The advantage is that oxygen and carbon dioxide diffuse much faster, 10,000 times faster, from the air than in water, blood or tissues. Unlike in mammals however, there is uncertainty as to whether the actions of carbon dioxide on insects result from a specific effect of this agent, from anoxia (reduced oxygen levels), and/or pH variations. What is known, is that with increasing levels of carbon dioxide, narcosis will occur, followed ultimately by death. <u>Resistance:</u> This test does not give any indication of resistance. In fact, resistance would not be expected with the use of carbon dioxide as an insecticide as it is lethal to the target insects in a single dose. As such, there is no mechanism for resistance to develop because target organisms are never exposed to sub-lethal concentrations of carbon dioxide (as a biocide).	A5.3/26

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference *)
Insecticide	Product type 18	Carbon dioxide (specification identical to that given in section 2 of application)	*Blatella germanica* German cockroach	Four numbered jars were prepared containing known numbers of various life stages of *B. germanica*. Jars 1 and 3 contained 20 nymphs of >4mm and 5 measuring <3mm. Jars 2 and 4 contained 5 adult males and 5 gravid adult females. Jars were fitted with mesh lids to allow for diffusion of gas. Jars 1 and 4 were placed inside the prefabricated fumigation bubble prior to filling with CO_2. Jars 2 and 3 were left adjacent to fumigation bubble as controls. CO_2 levels were measured periodically through the treatment and once 60% CO_2 levels had been achieved, 33 days were allowed to pass before fumigation bubble was dismantled. CO_2 levels were measured using an aspirator pump (Siebetec ST123) and Dräger measuring tubes. After ventilation of the bubble, the jars were collected and stored at 25°C for 7 days to allow for any recovery.	Atmosphere = 60% CO_2: 40% air Exposure time:33 days Temperature & RH not recorded.	100% mortality achieved after 33 days. <u>Mode of action:</u> Most insects respire by means of a tracheal system. In this system, gas is directly transported to the tissues by air-filled tubules that bypass blood. The pores to the outside, called spiracles, deliver the gases of respiration. The drawback of this system is that the gases diffuse slowly in the long narrow tubules; as a result, these tubes need to be limited in size for adequate gas transfer. The advantage is that oxygen and carbon dioxide diffuse much faster, 10,000 times faster, from the air than in water, blood or tissues. Unlike in mammals however, there is uncertainty as to whether the actions of carbon dioxide on insects result from a specific effect of this agent, from anoxia (reduced oxygen levels), and/or pH variations. What is known, is that with increasing levels of carbon dioxide, narcosis will occur, followed ultimately by death. <u>Resistance:</u> This test does not give any indication of resistance. In fact, resistance would not be expected with the use of carbon dioxide as an insecticide as it is lethal to the target insects in a single dose. As such, there is no mechanism for resistance to develop because target organisms are never exposed to sub-lethal concentrations of carbon dioxide (as a biocide).	A5.3/27