Section A1 **Applicant**
Annex Point IIA1

Official use only

1.1 Applicant

Name: [redacted]
Address: Rentokil Initial plc, Felcourt, East Grinstead, West Sussex RH19 2JY United Kingdom
Telephone: +44 (0)1342 833022
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e-mail address: [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)

1) Product 1 (*called Radar*) As above.

Section A2 **Identity of Active Substance**

Annex Point IIA II

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)	Carbon dioxide is obtained industrially as a by-product of hydrogen production. A summary of this process is given at the end of this document, and in data end point Document IIIA Section 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".	
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

Summary of Manufacturing process for Carbon Dioxide

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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[redacted]

Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	**Give date of action**
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	Attached report "Manufacture of carbon dioxide" gives details of the manufacturing process for carbon dioxide.	
ii) Workplace description	Attached report "Manufacture of carbon dioxide" gives details of the workplace where carbon dioxide is manufactured.	
iii) Inhalation exposure	There is no quantitative medical surveillance data available about worker exposures, however a qualitative assessment indicates that worker exposures to carbon dioxide during its manufacture is effectively nil. [redacted] [redacted]	
iv) Dermal exposure	Carbon dioxide is a gas. The principle route of exposure is via inhalation. Exposure via the dermal route is effectively nil.	
2.10.2 Intended uses **1. Professional users**		
i) Description of application process	Carbon dioxide is intended for use in the rodenticidal product, Radar. (PT14). Radar is a mouse trap that is designed to be placed along wall-floor junctions where mice are likely to run. The unit has entrances at each end through which mice can enter. Once inside, the mouse activates a pressure pad which causes the doors to shut, trapping the mouse inside, creating an effectively sealed chamber. In the same action that closes the doors, a second mechanism causes carbon dioxide to be totally released from an aerosol canister, which humanely kills the mouse inside the unit. The aerosol canister used in the Radar unit contains 3.0g of pressurised carbon dioxide. When the Radar unit is activated, the gas is released from the aerosol and expands to fill the chamber. The Radar unit is sufficiently airtight to contain the carbon dioxide until the rodent succumbs, after which the carbon dioxide slowly ventilates from the Radar unit, directly to atmosphere. Refer to Document IIIB, Section 6.6 for full details of the use pattern and expected levels of carbon dioxide exposure expected from the normal use of Radar by professional users.	
ii) Workplace description	Carbon dioxide is intended for use in the rodenticidal product, Radar. (PT14). Refer to Document IIIB, Section 6.6 for full details of the use pattern and expected levels of carbon dioxide exposure expected from the normal use of Radar by professional users.	

iii) Inhalation exposure	Carbon dioxide is intended for use in the rodenticidal product, Radar. (PT14). Refer to Document IIIB, Section 6.6 for full details of the use pattern and expected levels of carbon dioxide exposure expected from the normal use of Radar by professional users.	
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 in the rodenticidal product, Radar. (PT14). Radar is intended for use by professional users only, so primary exposure to carbon dioxide to non-professional users e.g. the general public is not applicable for the exposure assessment. However secondary (by-stander) exposure to carbon dioxide from its use as a biocide has been considered. Full details of the levels of secondary exposure to carbon dioxide expected from the use of the biocidal product, Radar is given in Document IIIB, Section 6.6	
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.	
iii) via drinking water	Carbon dioxide is intended for use in the rodenticidal product, Radar. (PT14). Radar is not intended for application directly to water courses, so exposure to carbon dioxide via drinking water is nil. Notwithstanding this, the environmental exposure assessment for Radar shows that there is no mechanism for carbon dioxide enter water courses during the normal use of Radar as a biocide. Full details of the expected levels of exposure to the aquatic compartment are given in section 2.10.2 (below).	
iv) via food	Carbon dioxide is intended for use in the rodenticidal product, Radar. (PT14). Radar is not intended for application directly to food, animal feeding stuffs or food contact surfaces, so exposure to carbon dioxide via food is nil.	
v) indirect via the environment	Carbon dioxide is intended for use in the rodenticidal product, Radar. (PT14). The environmental exposure assessment (as given in section 2.10.2, below) shows that the use of carbon dioxide in the rodenticidal product, Radar does not increase carbon dioxide concentrations above that found naturally in the environment. Given this, indirect human exposure to carbon dioxide via the environment has not been considered further.	
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 attached report "Manufacture of carbon dioxide"	
(ii) Releases into air	Refer to attached report "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 attached report "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):	None. Carbon dioxide is intended for use in the rodenticidal product, Radar. (PT14). The environmental exposure assessment for Radar shows that there will be zero exposure to the atmosphere, aquatic environment and sediment. Full details are given in Document IIIB, Section 7.1.
Predicted concentration in the environmental compartment(s):	Zero (other than that found naturally in the environment). Carbon dioxide is intended for use in the rodenticidal product, Radar. (PT14). The environmental exposure assessment for Radar shows that there will be zero exposure to the atmosphere, aquatic environment and sediment. Full details are given in Document IIIB, Section 7.1.

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.*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on assessment of materials and methods include appropriate reliability indicator.*
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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	0 [redacted]	[redacted] [redacted]	

Footnotes

[redacted]

Remarks/ Justification

Melting point is defined as the temperature at which the phase transition from solid to liquid occurs at atmospheric pressure. At atmospheric pressure, the solid form of carbon dioxide changes into the gaseous phase without liquefaction. Melting point data is therefore not relevant for carbon dioxide. Sublimation temperature for carbon dioxide is quoted widely in standard references, including those cited here. Note that the sublimation temperature quoted is at 760 mm Hg. [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 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]	[redacted] [redacted]	

Footnotes

[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
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 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 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]	

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 tendancy 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 it is being used as a biocide. Determining the Henry's Law constant 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 Henry's Law Constant is technically not possible to perform. This study is also not scientifically necessary.	None.	

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.							
3.3.2 Colour	Colourless.							
3.3.3 Odour	Odourless.							

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
3.4 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

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]	[redacted]	[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
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

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]	[redacted]	[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**
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 oC [redacted] [redacted] [redacted]	[redacted]	N	0: Not applicable. [redacted]	[redacted] [redacted]	
Effects of pH on water solubility	Refer to next page for details.							

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, so the equilibrium position would change so that the number of dissociated hydrogen ions was reduced by them recombining with the carbonate and bicarbonte ions, forming more carbonic acid. The 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, so the equilibrium position would change so that the number of dissociated hydrogen ions was increased by dissociating more carbonic acid molecules to form 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]	[redacted]	

<u>Footnotes</u>

[redacted]

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]	

Section A3 Physical and Chemical Properties of Active Substance

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 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

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 1/20cm^3 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 cm^3 CO_2/litre cyclohexanol (at 26°C pressure 766 mmHg).	[redacted]	N	2	[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
3.7 **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]	

[redacted]

Section A3 Physical and Chemical Properties of Active Substance

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.**	See below	

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

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
3.8 **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

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]

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] [redacted]	N	3	[redacted]	

[redacted]

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 the partition coefficient of carbon dioxide will be effected by pH and temperature. 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 will have 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 is not considered necessary for the following reasons. 1. It is not scientifically necessary on the basis of low exposure to carbon dioxide during its normal use as a biocide. 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*. Partition coefficient values are a key parameter in determining the environmental fate of chemicals, because it has been found to be related to water solubility, soil/sediment adsorption coefficients and bioconcentration factors for aquatic life [1]. As the environmental risk assessment for carbon dioxide shows that carbon dioxide concentrations do not increase outside normal atmospheric ranges when carbon dioxide is used as a rodenticide, consideration of the effect of pH and temperature on partition coefficient is not necessary. **Refer to next page for full details of the scientific calculation, which supports this statement.* 2. In addition to the above, the potential for environmental exposure to carbon dioxide when it is manufactured for use as a rodenticide is minimal. [redacted] 3. 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.	

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1. For references see next page.
2. For references see next page.

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] [redacted] [redacted] [redacted] [redacted] [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**
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 oC at 0.02 atm, 320-480 oC at 1 atm and 405-630 oC at 100 atm. At higher temperatures in each case, carbon is also formed but always in the presence of some oxygen. $CO_2 \leftrightarrow CO + 1/2 O_2$	[redacted]	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]	

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.	

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]	

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

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

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]	

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]	

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**
3.17 Reactivity towards container material (IIA3.13)	Carbon dioxide is supplied in containers [redacted] Containers manufactured to this specification will ensure that there is no reactivity between the carbon dioxide and its container. [redacted] [redacted]							

Section A4 (4.1-4.3) **Annex Point IIA4.1/4.2 & IIIA-IV.1**	**Analytical Methods for Detection and Identification** *Specify where appropriate, e.g. isomer of a.s., metabolite of a.s., impurity of a.s., matrix*	
	1 REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection	No	
1.2.1 Data owner	[redacted]	
1.2.2		
1.2.3 Criteria for data protection	No data protection claimed	
	2	
2.1		
2.2		
2.3		
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment	Non-entry field	
3.1.1 Enrichment	Flush both cylinder valves with liquid carbon dioxide and thoroughly purge the sample point with the liquid carbon dioxide to be sampled. Connect the non-syphon valve to the sample point using suitable connections. Hold the cylinder vertically with the syphon valve uppermost and open the non-syphon vale to pressurise the cylinder. Slowly open the syphon valve and fill the cylinder with liquid carbon dioxide by blowing off first gas and then carbon dioxide snow. Disconnect the cylinder and blow off approximately one fifth of the carbon dioxide from the gas phase through the non-syphoned valve in the uppermost position. Shake the cylinder and blow off the remaining carbon dioxide through the non-syphoned valve in the lower position. Reconnect the sample cylinder to the sample point and, holding the cylinder vertically with the syphoned valve uppermost, open the non-syphon valve to pressurise the cylinder. Slowly open the syphon valve and fill the cylinder with liquid carbon dioxide by blowing off first gas then carbon dioxide snow. Continue blowing snow from the syphoned valve for about 1 minute and then isolate the sample by turning off first the syphoned valve then the non-syphoned valve. Hold the cylinder vertically and, with the syphon valve uppermost, open the syphoned valve several times until only carbon dioxide gas is discharged from it. The free end of the syphon tube will then be just above the liquid carbon dioxide level in the cylinder. Allow the sample to equilibrate to room temperature prior to analysis. Analyse the sample as soon as is practicable after this thermal equilibrium is obtained.	

Section A4 (4.1-4.3) **Annex Point IIA4.1/4.2 & IIIA-IV.1**	**Analytical Methods for Detection and Identification** *Specify where appropriate, e.g. isomer of a.s., metabolite of a.s., impurity of a.s., matrix*	
	To withdraw the sample for analysis support the sampling cylinder vertically with the syphoned valve uppermost. Connect the non-syphoned valve of the sampling cylinder (liquid carbon dioxide) to an evaporating device and then via a control valve to the analytical apparatus. Thoroughly purge the connections valves and the evaporating device before starting the analysis.	
3.1.2 Cleanup	Not applicable	
3.2 Detection	Non-entry field	
3.2.1 Separation method	Product being sampled is nominally pure carbon dioxide. The following describes how to separate any residual gases from the carbon dioxide. The same reference also provides details of how to detect any oil, water, nitric oxide, and nitrogen dioxide **Reagents:** Potassium hydroxide solution approximately 600g/l Mercury clean, dry and free from grease Use a test sample of about 300ml for each determination See diagram in A4.1 **Procedure for 0%v/v to 0.0300%v/v residual gases:** Clean and dry the burette and grease the stopcocks. Fill the reservoir with mercury through stopcock B with stopcock A open. Allow a few millilitres of mercury to enter the potassium hydroxide reservoir. Close stopcock A. Pour about 10ml of the potassium hydroxide solution into the potassium hydroxide reservoir. Open stopcock A and adjust the mercury level so that no mercury is left in the potassium hydroxide reservoir or in the stopcock. The bore of stopcock A should be full of potassium hydroxide solution. Reverse stopcock A. Raise the mercury reservoir and completely fill the glass delivery line with mercury. Close stopcock A. Connect a short length of glass impermeable, flexible tubing to the exit of the evaporating device. Purge this flexible tubing with the carbon dioxide test sample. Connect the flexible tubing to the glass delivery line of the burette and, by lowering the mercury reservoir with stopcock A open, introduce carbon dioxide through stopcock A into the gas burette. When only a few millimetres of mercury remain in the gas burette, turn stopcock B so that this small quantity of mercury in the stopcock is discarded through the carbon dioxide purge line. Continue purging the carbon dioxide through the apparatus for about 2 minutes. Close stopcock A and disconnect the sample delivery line. Quickly close stopcock B. Adjust the level of the mercury reservoir, with stopcock B open, to give slight negative pressure in the burette and then open stopcock A to the potassium hydroxide reservoir. Allow about 5 ml of the potassium hydroxide solution to enter the burette. Close stopcock A. Raise the mercury reservoir during the absorption of the carbon dioxide to maintain a slight positive pressure on the burette. Make small additions of potassium hydroxide solution towards the end of the absorption by suitable manipulation of the mercury reservoir and stopcock A. Ease the remaining bubble of residual gas into the capillary measuring	

Section A4 (4.1-4.3) **Annex Point IIA4.1/4.2 & IIIA-IV.1**	**Analytical Methods for Detection and Identification** *Specify where appropriate, e.g. isomer of a.s., metabolite of a.s., impurity of a.s., matrix*	
	section of the burette by manipulation of the mercury reservoir and stopcock A. Level off the mercury columns and then measure the length of the bubble of residual gas in mm. **Procedure for 0.03%v/v to 1.00%v/v residual gases:** Clean and dry the burette and grease the stopcocks. Fill one reservoir with the potassium hydroxide solution and fill the other reservoir with water. Raise the water reservoir and open the stopcock D to connect the water reservoir to the burette. Open stopcock C and allow water to fill the burette completely. Close stopcock C. Connect a short length of glass impermeable, flexible tubing to the exit of the evaporating device. Purge this flexible tubing with the carbon dioxide test sample, connect to stopcock C and allow the sample to displace all the water from the burette. When all the water has been displaced allow the test sample to bubble through the water reservoir for 15 to 30 seconds. Close stopcock C and disconnect the flexible tubing. The burette will now be under a slight positive pressure from the water reservoir. Carefully open stopcock C to atmosphere until the water in the tubing, connecting the water reservoir to the burette, reaches stopcock D. Close stopcock C and stopcock D. Open stopcock D to connect the potassium hydroxide reservoir to the burette. Allow the potassium hydroxide solution to flow into the burette. Use gentle agitation to assist the absorption of the carbon dioxide. Manipulate the bubble of residual gases into the measuring section of the burette. Level off the potassium hydroxide solution in the reservoir with the bottom edge of the bubble and read off the volume of the residual gases in ml.	
3.2.2 Detector	There are many gas detection systems which will measure carbon dioxide levels. A very well known one is the Drager method which offers tubes which can detect carbon dioxide in the following ranges: 100-3000ppm and 0.1-6%v/v. Drager also offer electronic carbon dioxide detection systems which can measure carbon dioxide from 0 to 400ppm.	
3.2.3 Standard(s)	Not applicable	
3.2.4 Interfering substance(s)	Not applicable. There are separate methods for measuring residual gases, water, nitric oxide and nitrogen dioxide impurities and oil content.	
3.3 Linearity	Non-entry field	
3.3.1 Calibration range	Electronic is 0-400ppm, tubes 100 – 3000ppm	
3.3.2 Number of measurements	As required	
3.3.3 Linearity	Not applicable	
3.4 Specificity: interfering substances	Not applicable	
3.5 Recovery rates at	Not stated	

Section A4 (4.1-4.3) **Annex Point IIA4.1/4.2 & IIIA-IV.1**		**Analytical Methods for Detection and Identification** *Specify where appropriate, e.g. isomer of a.s., metabolite of a.s., impurity of a.s., matrix*	
	different levels		
3.5.1	Relative standard deviation	Not stated	
3.6	**Limit of determination**	Electronic 0-400ppm Tubes 100-3000ppm	
3.7	**Precision**	Non-entry field	
3.7.1	Repeatability	Not stated	
3.7.2	Independent laboratory validation	Not stated	
		4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1	**Materials and methods**	There are many widely available kits used for measuring carbon dioxide levels. [redacted] outlines how to measure for residual gases that may be found in the CO2, there are additional methods in the specification to measure for oil, water, nitric oxide and nitrogen dioxide that may be present.	
4.2	**Conclusion**	Methods of detection of carbon dioxide are satisfactory.	
4.2.1	Reliability	2	
4.2.2	Deficiencies	No *(If yes, discuss the relevance of deficiencies and acceptability of study.)*	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub)heading numbers and to the applicant's summary and conclusion.*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of the method include appropriate reliability indicator*

Section A4 (4.1-4.3) **Annex Point IIA4.1/4.2 & IIIA-IV.1**	**Analytical Methods for Detection and Identification** *Specify where appropriate, e.g. isomer of a.s., metabolite of a.s., impurity of a.s., matrix*
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 the comments submitted*
Results and discussion	*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*
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 A4 (4.1) **Annex Point IIA, IV.4.1**	**Analytical Methods for Detection and Identification** *Impurity content*	
	1 REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection	Not relevant	
1.2.1 Data owner	Not relevant	
1.2.2		
1.2.3 Criteria for data protection	Not relevant	
	2	
2.1		
2.2		
2.3		
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment	Non-entry field	
3.1.1 Enrichment	[redacted]	
3.1.2 Cleanup	[redacted]	
3.2 Detection	Non-entry field	
3.2.1 Separation method	[redacted]	
3.2.2 Detector	[redacted]	
3.2.3 Standard(s)	[redacted]	
3.2.4 Interfering substance(s)	[redacted]	
3.3 Linearity	Non-entry field	
3.3.1 Calibration range	[redacted]	
3.3.2 Number of measurements	[redacted]	

Section A4 (4.1) **Annex Point IIA, IV.4.1**	**Analytical Methods for Detection and Identification** *Impurity content*	
3.3.3 Linearity	[redacted]	
3.4 Specificity: interfering substances	[redacted]	
3.5 Recovery rates at different levels	[redacted]	
3.5.1 Relative standard deviation	[redacted]	
3.6 Limit of determination	[redacted]	
3.7 Precision	Non-entry field	
3.7.1 Repeatability	[redacted]	
3.7.2 Independent laboratory validation	[redacted]	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	[redacted]	
4.2 Conclusion	[redacted]	
4.2.1 Reliability	[redacted]	
4.2.2 Deficiencies	Not relevant.	

Section A4 (4.1) **Annex Point IIA, IV.4.1**	**Analytical Methods for Detection and Identification** *Impurity content*
	Evaluation by Competent Authorities
	Use separate “evaluation boxes” to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	*State if the applicant’s version is acceptable or indicate relevant discrepancies referring to the (sub)heading numbers and to the applicant’s summary and conclusion.*
Conclusion	*Adopt applicant’s version or include revised version*
Reliability	*Based on the assessment of the method 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 the comments submitted*
Results and discussion	*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*
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 A4 (4.3) **Annex Point IIIA, IV.1**	**Analytical Methods for Detection and Identification** *Analytical methods relating to residues in /on soil, air or water.*	
	1 REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection	Not relevant	
1.2.1 Data owner	Not relevant	
1.2.2		
1.2.3 Criteria for data protection	Not relevant	
	2	
2.1		
2.2		
2.3		
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment	Non-entry field	
3.1.1 Enrichment	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.1.2 Cleanup	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.2 Detection	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.2.1 Separation method	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.2.2 Detector	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.2.3 Standard(s)	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed	

Section A4 (4.3) **Annex Point IIIA, IV.1**	**Analytical Methods for Detection and Identification** *Analytical methods relating to residues in /on soil, air or water.*	
	justification at end of section.	
3.2.4 Interfering substance(s)	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.3 Linearity	Non-entry field.	
3.3.1 Calibration range	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.3.2 Number of measurements	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.3.3 Linearity	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.4 Specificity: interfering substances	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.5 Recovery rates at different levels	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.5.1 Relative standard deviation	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.6 Limit of determination	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.7 Precision	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.7.1 Repeatability	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
3.7.2 Independent laboratory validation	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	

Section A4 (4.3) **Annex Point IIIA, IV.1**	**Analytical Methods for Detection and Identification** *Analytical methods relating to residues in /on soil, air or water.*	
4.2 Conclusion	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
4.2.1 Reliability	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	
4.2.2 Deficiencies	Not relevant as there is no detectable elevation in the level of carbon dioxide in air and consequently soil and water. See detailed justification at end of section.	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub)heading numbers and to the applicant's summary and conclusion.*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of the method 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 the comments submitted*
Results and discussion	*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*
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	

Detailed justification:	[redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted]
Undertaking of intended data submission [ ]	Not applicable

Section A4 (4.2) **Annex Point IIA, IV.4.2**	**Analytical Methods for Detection and Identification** *Analytical methods relating to animal and human body fluids and tissues*	
	1 REFERENCE	Official use only
1.1 Reference	Not required as active substance is not classified as toxic or highly toxic.	
1.2 Data protection	Not relevant	
1.2.1 Data owner	Not relevant	
1.2.2		
1.2.3 Criteria for data protection	Not relevant	
	2	
2.1		
2.2		
2.3		
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment	Non-entry field	
3.1.1 Enrichment	Not required as active substance is not classified as toxic or highly toxic.	
3.1.2 Cleanup	Not required as active substance is not classified as toxic or highly toxic.	
3.2 Detection	Non-entry field	
3.2.1 Separation method	Not required as active substance is not classified as toxic or highly toxic.	
3.2.2 Detector	Not required as active substance is not classified as toxic or highly toxic.	
3.2.3 Standard(s)	Not required as active substance is not classified as toxic or highly toxic.	
3.2.4 Interfering substance(s)	Not required as active substance is not classified as toxic or highly toxic.	
3.3 Linearity	Non-entry field	
3.3.1 Calibration range	Not required as active substance is not classified as toxic or highly toxic.	
3.3.2 Number of measurements	Not required as active substance is not classified as toxic or highly toxic.	

Section A4 (4.2) **Annex Point IIA, IV.4.2**	**Analytical Methods for Detection and Identification** *Analytical methods relating to animal and human body fluids and tissues*	
3.3.3 Linearity	Not required as active substance is not classified as toxic or highly toxic.	
3.4 Specificity: interfering substances	Not required as active substance is not classified as toxic or highly toxic.	
3.5 Recovery rates at different levels	Not required as active substance is not classified as toxic or highly toxic.	
3.5.1 Relative standard deviation	Not required as active substance is not classified as toxic or highly toxic.	
3.6 Limit of determination	Not required as active substance is not classified as toxic or highly toxic.	
3.7 Precision	Non-entry field	
3.7.1 Repeatability	Not required as active substance is not classified as toxic or highly toxic.	
3.7.2 Independent laboratory validation	Not required as active substance is not classified as toxic or highly toxic.	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	Not required as active substance is not classified as toxic or highly toxic.	
4.2 Conclusion	Not required as active substance is not classified as toxic or highly toxic.	
4.2.1 Reliability	Not required as active substance is not classified as toxic or highly toxic.	
4.2.2 Deficiencies	Not relevant.	

Section A4 (4.2) **Annex Point IIA, IV.4.2**	**Analytical Methods for Detection and Identification** *Analytical methods relating to animal and human body fluids and tissues*
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub)heading numbers and to the applicant's summary and conclusion.*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of the method 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 the comments submitted*
Results and discussion	*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*
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 A4 (4.3) **Annex Point IIIA, IV.1**	**Analytical Methods for Detection and Identification** *Analytical methods relating to residues in /on food or feedstuffs*	
	1 REFERENCE	Official use only
1.1 Reference	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
1.2 Data protection	Not relevant	
1.2.1 Data owner	Not relevant	
1.2.2		
1.2.3 Criteria for data protection	Not relevant	
	2	
2.1		
2.2		
2.3		
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment	Non-entry field	
3.1.1 Enrichment	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.1.2 Cleanup	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.2 Detection	Non-entry field	
3.2.1 Separation method	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.2.2 Detector	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.2.3 Standard(s)	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.2.4 Interfering substance(s)	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.3 Linearity	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.3.1 Calibration range	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.3.2 Number of measurements	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	

Section A4 (4.3) **Annex Point IIIA, IV.1**	**Analytical Methods for Detection and Identification** *Analytical methods relating to residues in /on food or feedstuffs*	
3.3.3 Linearity	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.4 Specificity: interfering substances	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.5 Recovery rates at different levels	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.5.1 Relative standard deviation	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.6 Limit of determination	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.7 Precision	Non-entry field	
3.7.1 Repeatability	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
3.7.2 Independent laboratory validation	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
4.2 Conclusion	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs. In addition Carbon dioxide is an approved food additive in the European Union. It has been assigned the number E290 and is used widely as a food preservative. Carbon dioxide is also used extensively in the drinks industry as it provides the effervescence in carbonated drinks. Carbon dioxide's status as an approved food additive in both the EU and the USA (where it is also an approved food additive with "Generally Regarded as Safe (GRAS) status) indicates that carbon dioxide is considered to be safe for human consumption.	
4.2.1 Reliability	Not required as active substance is not intended to be used in a manner that may cause contact with food or feedstuffs.	
4.2.2 Deficiencies	Not relevant.	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE

Section A4 (4.3) **Annex Point IIIA, IV.1**	**Analytical Methods for Detection and Identification** *Analytical methods relating to residues in /on food or feedstuffs*
Date	*Give date of action*
Materials and methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub)heading numbers and to the applicant's summary and conclusion.*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of the method 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 the comments submitted*
Results and discussion	*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*
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	

		1. REFERENCE		Official use only
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:	$r^2 = 0.9912$
		Asco Method:	$r^2 = 0.9999$
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	Infrared Analysis:	
		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 %
		Asco method:	
		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.	

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** [4]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [ ]	
Detailed justification:	The environmental risk assessment shows that carbon dioxide, when used as a biocide, does not enter the soil compartment because there is no mechanism for the carbon dioxide to be released directly into the soil given that it is a gas. 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**	
	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** [4]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [ ]	
Detailed justification:	The environmental risk assessment shows that carbon dioxide, when used as a biocide, does not enter the aquatic compartment. This means that the use of carbon dioxide, when used as a biocide, does not affect the levels of carbon dioxide found naturally in the environment, outside normal atmospheric levels. *(Refer to next page for the scientific justification which supports this statement.).* As demonstrated, an analytical method for the detection of carbon dioxide in water is not necessary due to the pre-requisites fulfilled on limited exposure and toxicity profile. (Continued,……)	

Section 4.2 **Annex Point IIA, IV 4.2**	**Analytical Methods for Detection and Identification in Environmental Media: Water**

Detailed justification:	[redacted] [redacted] [redacted] [redacted]
Undertaking of intended data submission [ ]	Not applicable

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

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

Section 4.2 **Annex Point IIA, IV 4.2**	**Analytical Methods for Detection and Identification in Environmental Media: Animal and Human Body Fluids and Tissues**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [4]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	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.	
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** [4]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [ ]	
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. It is not necessary to submit an analytical method for the determination of carbon dioxide in/on food or feeding stuffs or other products because carbon dioxide (or the representative product RADAR) is not intended for use on soils used for agriculture or horticulture, or in areas where food for human consumption or feed for livestock is prepared, consumed or stored.	
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)**	Rodenticide.	
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)**	For the control of rats and mice, such as house mouse (*Mus domesticus*), brown rat (*Rattus norvegicus*), and black rat (*Rattus rattus*).	
5.2.2	**Products, organisms or objects to be protected. (IIA5.2)**	Rodent control has immeasurable benefits – preventing damage to the fabric of buildings, to electric wiring and plumbing. Rodent control also protects damage to food commodities. Rats and mice exist in all parts of the European Community, including Belgium, Denmark, Eire, Finland, France, Germany, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the UK.	
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**		
5.3.1	**Effects on target organism(s)**	When rats and mice are exposed to carbon dioxide in an enclosed chamber, they are initially knocked out by the narcotic effect of carbon dioxide (when the concentration reaches approximately 30%), and eventually killed (when the carbon dioxide concentration reaches approximately 70%). Refer to section 5.3 for details of screening test for carbon dioxide.	
5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**		
	PT 14	100% When used as a rodenticide, Carbon Dioxide is intended for use at concentrations of 100 % w/w. This in-use concentration will apply for all countries within the EU where Carbon Dioxide is used as a rodenticide. Use of Carbon Dioxide at 100 % w/w is necessary to ensure that the level of Carbon Dioxide needed to cause the death of the trapped rodent is reached as quickly, and as humanely, as possible.	

5.4	**Mode of action (including time delay) (IIA5.4)**	
5.4.1	**Mode of action**	It is known from the screening test (detailed in section 5.3) that rats and mice, when exposed to carbon dioxide, are initially knocked out by the narcotic effect of carbon dioxide (when the concentration reaches approximately 30%), and eventually killed (when the carbon dioxide concentration reaches approximately 70%). It is widely reported in the public domain that build-up of carbon dioxide in the blood leads to a condition called 'respiratory acidosis'. The first symptoms are drowsiness, leading to stupor and coma and ultimately death. This can happen very quickly if the carbon dioxide levels in the blood do not fall.
5.4.2	**Time delay**	In the screening test (detailed in section 5.3), three cans of carbon dioxide (containing a nominal 2.8g carbon dioxide) were tested in an enclosed chamber ('the unit'). All mice were killed within one minute after initial exposure to carbon dioxide.
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
	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 will be used as a rodenticide by professional users only e.g. pest control operators.
	General public	Carbon dioxide is not intended for use 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 *)
Rodenticide	Product type 14	Carbon dioxide (specification identical to that given in section 2 of application)	Wild-derived strain of house mice (*mus domesticus*). Weight: 14.5g to 17.8g	Three cans containing a nominal 2.8g of carbon dioxide were tested in an enclosed system (referred to as 'the unit'). The unit was connected to a carbon dioxide gas analyser by two airtight connections. A pump/recycle system ensured that the presence of the analyser did not influence the carbon dioxide concentration inside the unit. Carbon dioxide measurements were measured throughout the trial.	The unit was placed inside a 1 m^2 perspex arena, and a mouse was placed in the arena such that they entered the unit, activating the mechanism by stepping on a pressure pad inside. Three mice from a wild-derived colony (body weight 14.5-17.8g) were used. Time to immobility (unconsciousness), last breath (death) and any other symptoms observed were noted for each mouse. After five minutes, the mice were removed from the unit. Tail and toe pinches were conducted to corroborate the death of the animal, which was observed for 30 minutes to confirm there were no signs of recovery. The concentration of carbon dioxide in the unit was monitored for the 5 minutes the mice were inside.	The concentrations of carbon dioxide reached within the first minute of exposure (maximum 65-67% carbon dioxide) were more than sufficient to ensure that the trapped mice would be killed reliably and humanely. The results to the test support literature data which indicates that mice are initially knocked out by the narcotic effect of carbon dioxide when the concentration reaches 30%, and eventually killed when the concentration reaches 70%. Results do not give an indication about development of resistance.	[redacted] [redacted]

EXPLANATION OF THE DOSE OF 2.8g CARBON DIOXIDE IN THE REPRESENTATIVE PRODUCT, RADAR

The RADAR unit is a mousetrap that is designed to be placed along wall floor junctions where mice are likely to run. The unit has entrances at each end through which mice can enter. Once inside, the mouse activates a pressure pad which causes the doors to shut, trapping the mouse inside, creating a sealed chamber. In the same action that closes the doors, a second mechanism causes CO_2 to be totally released from an aerosol canister, which humanely kills the mouse inside the trap. The UK Home Office currently recommends the use of carbon dioxide in a rising concentration as a humane method of killing rodents up to 1.5 kg. Mice are initially knocked out by the narcotic effects of carbon dioxide when the concentration reaches 30% and eventually killed when the concentration reaches 70%.[2] The dimensions of the RADAR unit are clearly defined to ensure that the unit's length is adequate to guarantee that once the unit is triggered, the mouse –including tail -is completely inside the unit so that the animal can be dispatched quickly and humanely. The volume of carbon dioxide required to reach the 70% threshold limit specified by the UK Home Office was calculated. Different weights of animals were tested in the unit to ensure that all animals are killed quickly and humanely. Test data shows that when aerosols containing 2.35g, 2.36g and 2.38g carbon dioxide were used in the RADAR unit, carbon dioxide concentrations reached 65-67% when the unit was tripped. This concentration was sufficient to kill mice weighing 14.5g – 17.8g within one minute of the RADAR unit being tripped.[1] However, it is not acceptable to allow any possibility for failure to kill trapped mice (trapping a mouse without killing it would be clearly unacceptable). Therefore, in order to ensure an adequate safety margin for manufacturing tolerances and different weights of mice, aerosols are supplied for use in the RADAR unit containing 2.8g carbon dioxide. Any environmental or non-target risks posed by the extra carbon dioxide are far outweighed by the increase in reliable efficacy.

[redacted]

[redacted]

Subsection (Annex Point)		Official use only
5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)		
5.7.1 Development of resistance	Resistance of pests to pesticides is defined as the ability of a given population to withstand a poison that was effectively lethal to earlier generations of the species. Resistance to carbon dioxide will not develop because, when used as a biocide, it will be lethal to the target rodent in a single dose (as demonstrated by the information submitted for the representative product containing carbon dioxide, Radar). This means that there is no mechanism for resistance to carbon dioxide to develop because target organisms are never exposed to sub-lethal concentrations of carbon dioxide (as a biocide), unlike the multi-feed pesticides such as anticoagulant rodenticides.	
5.7.2 Management strategies	Given the fact that resistance to carbon dioxide cannot develop because of the way it is used (see above), a management strategy for the control of the development of resistance to carbon dioxide has not been proposed.	
5.8 Likely tonnage to be placed on the market per year (IIA5.8)	[redacted] [redacted] [redacted] [redacted]	

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

Section 6.1.1 **Annex Point IIA, VI, 6.1.1**	**Acute Toxicity : Oral** Section 6: Toxicological and Metabolic Studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only

Section 6.1.1 **Annex Point IIA, VI, 6.1.1**	**Acute Toxicity : Oral** Section 6: Toxicological and Metabolic Studies

Other existing data [ ]	**Technically not feasible** [4]	**Scientifically unjustified** [ ]	
Limited exposure [4]	**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. In addition, the "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that acute toxicity of gases and volatile liquids should be determined by the inhalation route only. As carbon dioxide is a gas, acute toxicity by the oral route is not required under the Biocidal Products Directive.

Notwithstanding the above, it is not considered necessary to determine the toxicity of carbon dioxide by the oral route for three reasons:

1. It is not scientifically necessary on the basis of low exposure to carbon dioxide during it's normal use as a biocide. 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.
   Refer to next page for full details of the scientific calculation, which supports this statement.

2. In addition to the above, the potential for exposure to carbon dioxide when it is manufactured for use as a rodenticide is minimal. [redacted]

3. Carbon dioxide is an approved food additive in the European Union. It has been assigned the number E290 and is used widely as a food preservative. Carbon dioxide is also used extensively in the drinks industry as it provides the effervescence in carbonated drinks. Carbon dioxide's status as an approved food additive in both the EU and the USA (where it is also an approved food additive with "Generally Regarded as Safe (GRAS) status) indicates that carbon dioxide is considered to be safe for human consumption.

Continued………

Section 6.1.1 **Annex Point IIA, VI, 6.1.1**	**Acute Toxicity : Oral** Section 6: Toxicological and Metabolic Studies

Detailed justification:	[redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted]
Undertaking of intended data submission [ ]	Not applicable

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

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

Section 6.1.2 Annex Point IIA, VI, 6.1.2	**Acute Toxicity : Dermal** Section 6: Toxicological and Metabolic Studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.*	Official use only
Other existing data [ ] **Limited exposure** [4]	**Technically not feasible** [4] **Scientifically unjustified** [ ] **Other justification** [ ]	
Detailed justification:	It is not technically possible to determine the acute toxicity of carbon dioxide by the dermal route. In addition, the "Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products" states that acute toxicity of gases and volatile liquids should be determined by the inhalation route only. As carbon dioxide is a gas, acute toxicity by the dermal route is not required under the Biocidal Products Directive. Notwithstanding this, it should be noted that the some of the acute inhalation studies summarised in Section 6.1.3, and some of the repeated dose toxicity studies summarised in Section 6.3 and 6.4 were not 'nose-only' exposure. This means that some continuous dermal exposure would have occurred during these studies and contributed to the overall effect and end-point. It is not only technically not possible to determine the acute toxicity of carbon dioxide by the dermal route, but it is also not scientifically necessary on the basis of low exposure to carbon dioxide during it's normal use as a biocide. 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. *Refer to next page for full details of the scientific calculation, which supports this statement.* In addition to the above, the potential for exposure to carbon dioxide when it is manufactured for use as a rodenticide is minimal. [redacted] Continued……	