Section A1 **Applicant**

Annex Point IIA1

1.1	**Applicant**	Duke Faunabeheer
1.2	**Manufacturer of Active Substance** (if different)	Linde gas Benelux
1.3	**Manufacturer of Product(s) (if different)**	As above

Official use only

1 REFERENCE

1.1	**REFERENCE**	Duke Faunabeheer BV (2012) - Results of analyses of 5 batches of food grade carbon dioxide liquefied gas, manufactured by Linde Gas Benelux
1.2	**DATA PROTECTION**	Yes
1.2.1	**Data owner**	Duke Faunabeheer BV, Lelystad, The Netherlands
1.2.2	**Companies with letter of access**	Not applicable
1.2.3	**Criteria for data protection**	Data on new a.s. /PT combination for first entry to Annex IA

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**GUIDELINE STUDY**	Yes ISBT 2010. Bulk carbon dioxide quality guidelines and analytical methods reference (2nd revision). International Society of Beverage Technologists, Dallas, TX USA, November 2010, pg. 64 – 68: Carbon dioxide (CO_2) % purity by caustic absorption analysers. Published
2.2	**GLP**	No
2.3	**DEVIATIONS**	No

3 MATERIALS AND METHODS

3.1	**TEST MATERIAL**	Carbon dioxide
3.1.1	**Lot/Batch number**	376099981434633 376099981434701 376099981434764 376099981434944 376099981435303
3.1.2	**Specification**	Kooldioxide foodgrade EIGA/ISBT vloeibaar
3.1.3	**Appearance**	Colourless and odourless gas
3.2	**TEST METHOD**	
3.2.1	**Preparation of test substance for analysis**	No preparation required
3.2.2	**Methods**	Analyte-specific methods are described in detail in ISBT 2010.
3.2.3	**Analyte(s)**	CO_2, H_2O, NH_3, O_2, NO, NO_2, CH_3CHO, C_6H_6, CH_3OH, total Sulphur, CO, total volatile hydrocarbons, non-volatile residues (particles), non-volatile organic residues.
3.2.4	**Measurement range**	CO_2: 99.0 – 100.0 % v/v purity

RESULTS AND DISCUSSION

3.3 RESULTS

Batch number	CO_2 content (% v/v)
376099981434633	99.9
376099981434701	99.9
376099981434764	99.9
376099981434944	99.9
376099981435303	100.0

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**MATERIALS AND METHODS**	ISBT 2010. Bulk carbon dioxide quality guidelines and analytical methods reference (2nd revision). The analyses were performed by Linde Gas Benelux B.V., Europoort Rotterdam, The Netherlands
4.2	**RESULTS AND DISCUSSION**	5 batches of food grade CO_2 from Linde Gas Benelux were analysed following internationally accepted methods and criteria for food grade CO_2. The purity of the CO_2 was ≥ 99.9 % v/v.

Section A1.2 (01) Annex Point IIA2.7-2.8	5-batch analysis
4.3 CONCLUSION	All batches meet the requirements set by the European Industrial Gases Association (EIGA, 2008) for carbon dioxide for use in food and beverages.
4.3.1 Reliability	1
4.3.2 Deficiencies	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
DATE	December 2013
MATERIALS AND METHODS	*Applicant's version is acceptable.*
RESULTS AND DISCUSSION	*Applicant's version is acceptable.*
CONCLUSION	*Applicant's version is acceptable.*
REMARKS	The 5 batch data meet the requirements set by the European Industrial Gases Association (EIGA, 2008) for carbon dioxide for use in food and beverages and this considered to be sufficient.

Section A2 Identity of Active Substance

Subsection (Annex Point)			Official use only
2.1	**Common name (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**	CO_2	
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.	
2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	g/kg: g/l: % w/w: >99% carbon dioxide % v/v:	

Section A2 Identity of Active Substance

Kooldioxide foodgrade EIGA/ISBT vloeibaar

EIGA limiting characteristics for carbon dioxide for foods and beverages.

Component	Concentration
Assay	99.9% v/v min.
Moisture	50 ppm v/v max. (20 ppm w/w max.)
Ammonia	2.5 ppm v/v max.
Oxygen	30 ppm v/v max.
Oxides of Nitrogen (NO/NO2)	2.5 ppm v/v max. each
Non-volatile residue(particulates)	10 ppm w/w max.
Non-volatile organic residue (oil and grease)	5 ppm w/w max.
Phosphine ***	0.3 ppm v/v max
Total volatile hydrocarbons (calculated as methane)	50 ppm v/v max. of which 20 ppm v/v max non-methane hydrocarbons.
Acetaldehyde	0.2 ppm v/v max.
Benzene	0.02 ppm v/v max.
Carbon Monoxide	10 ppm v/v max.
Methanol	10 ppm v/v max.
Hydrogen Cyanide*	0.5 ppm v/v max
Total Sulphur (as S) **	0.1 ppm v/v max.
Taste and Odour in Water	No foreign taste or odour

* Analysis necessary only for carbon dioxide from coal gasification sources

** If the total sulphur content exceeds 0.1 ppm v/v as sulphur then the species must be determined separately and the following limits apply:
Carbonyl Sulphide 0.1 ppm v/v max.
Hydrogen Sulphide 0.1 ppm v/v max.
Sulphur Dioxide 1.0 ppm v/v max.

*** Analysis necessary only for carbon dioxide from phosphate rock sources

2.8 Identity of impurities and additives, as appropriate (IIA2.8)

No additives present in carbon dioxide.

No impurities present in carbon dioxide above the concentration limit of 1 g/kg.

No impurities of toxicological or ecotoxicological significance present below the concentration limit of 1 g/kg.

2.8.1 Isomeric composition

Not relevant. Carbon dioxide is made up of one carbon and two oxygen atoms which can only be combined in one way.

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

Although carbon dioxide is obtained industrially as a by-product of hydrogen production (refer to 2.6, above), it occurs naturally in the atmosphere. It is uniformly distributed in the atmosphere over the earth's surface at a concentration of about 0.033% or 330ppm.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	March 2013
Materials and methods	
Conclusion	Agree with the available information
Reliability	
Acceptability	
Remarks	

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
3.1 Melting point, boiling point, relative density (IIA3.1)								
3.1.1 Melting point	Not reported		- 78.5°C (sublimation temperature)	The information required for this data end point can be derived from existing data.	N		O'Neil et al (2001) Haynes and Lide (2011-2012)	acceptable
3.1.2 Boiling point	Not reported		- 78.5°C (sublimation temperature)	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	N/A		O'Neil et al (2001) Haynes and Lide (2011-2012)	acceptable

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
3.1.3 Bulk density/ relative density Bulk/rel. density 1	Not reported		Relative density: 1.527 The density is 1.977 g/l at 0°C and 1.799 g/l at 25°C and 101.325 Pa		N	0: Not applicable. Reliability cannot be assigned because No experimental data has been submitted to meet this end point. The information required for this end point was derived from existing data.	O'Neil et al (2001) Haynes and Lide (2011-2012)	acceptable
3.2 Vapour pressure (IIA3.2) Vapour pressure 1	N/A	N/A	N/A	Not applicable, as carbon dioxide is a gas. For liquefied carbon dioxide, the	N/A		Haynes and Lide (2011-2012)	acceptable

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
				vapour pressure is 6713 kPa at 300 K and 5984 kPa at 295 K.				
3.2.1 Henry´s Law Constant (Pt. I-A3.2)	N/A	N/A	The Henry's law constant is calculated with the following literature data: P: 6443 kPa at 25°C (interpolated) and solubility is 1.50 g/l at 25°C. The calculated value is: 189037 $Pa.m^3.mol^{-1}$		N/A			acceptable
3.3 Appearance (IIA3.3)								
3.3.1 Physical state	Not reported		gas at room temperature		N	Not applicable.	O'Neil et al (2001); AIGA (2009)	acceptable

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
	Not reported		Colourless		N	Not applicable.	O'Neil et al (2001); AIGA (2009)	acceptable
3.3.3 Odour	Not reported		Odourless		N	Not applicable.	O'Neil et al (2001); AIGA (2009)	
3.4 Absorption spectra (IIA3.4)								acceptable.
UV/VIS			140 nm		N		Thompson BA, Harteck P, Reeves RR Jnr (1963)	acceptable.
IR			2349 cm^{-1} (4.26 um) and at 667 cm^{-1} (15.00 um).		N		Stein SE (2001)	acceptable.

NMF

NMR			124.2 ppm (^{13}C NMR chemical shift, relative to TMS).		N		Stothers JB (1972); Ettinger R, Blume P, Patterson A (1960)	acceptable.
MS			MS: fragments at m/z 12, 16, 22, 28, 44, 45		N		Stein SE (2001)	acceptable.

3.5 Solubility in water (IIA3.5)								
Water solubility 1	Not reported – refer to remarks / justification.	.	Carbon dioxide is very slightly soluble in water. 0.20% at 15° C 0.17 % at 20° C 0.15 % at 25° C 0.13% at 30° C 0.12 % at 35° C	The water solubility data provided has been sourced from data found in the public domain. Experimental determination of the water solubility of the carbon dioxide prescribed in this application will not add any new information to the huge volume of phys-chem data available for carbon dioxide which is in broad agreement regarding the accepted water solubility for carbon dioxide.	N	Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point. The information required for this data end point can be derived from existing data.	Haynes and Lide (2011-2012)	Acceptable
Water solubility 2			Solubility of carbon dioxide in water: 0 °C and 760 mm pressure: 1,710 cm^3 CO_2 / L (equivalent to 171 ml CO_2 in 100 ml water). 20 °C and 760 mm pressure: 880 cm^3 CO_2 / L (equivalent to 88 ml CO_2 in 100 ml water). 60 °C and 760 mm pressure: 360 cm^3 CO_2 / L (equivalent to 36 ml CO_2 in 100 ml water). Refer to document entitled "Solubility of Carbon Dioxide in water" for full details.				O'Neil et al (2001)	

3.6	**Dissociation constant (-)**	N/A	N/A	N/A	Carbon dioxide is a gas under the conditions it will be marketed as a biocide. It is not technically feasible to determine the dissociation constant for a gas. There is no approved guideline for testing the dissociation constant of a gas. Notwithstanding this, it is not necessary to determine the dissociation constant of carbon dioxide on the basis of limited exposure to the environment.	N/A	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. This study is also not necessary due to prerequisites fulfilled on limited exposure and toxicity profile.	United States Environmental Protection Agency (1996) EPA Product Properties Test Guidelines OPPTS 830.7370 Dissociation Constants in Water EPA 712-C-96-036	acceptable
3.7	**Solubility in**	Solubility in	The CO_2 used	Results presented in	The information	N	2	Battino R,	

organic solvents, including the effect of temperature on solubility (IIIA3.1)	isobutanol.	was the purest that was commercially available (>99 moles per cent), and came from the Matheson Co. Inc.	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.	required for this data end point can be derived from existing data. The data provided about solubility in isobutanol has been sourced from data found in the public domain. Experimental determination of the isobutanol-solubility of the carbon dioxide prescribed in this application will not add any new information to the huge volume of phys-chem data available for carbon dioxide which is in broad agreement regarding the accepted isobutanol-solubility for carbon dioxide.			Evans FD, Danforth WF, and Wilhelm E (1971)	
	Solubility in	Specification		The information	N	2	Cauquil G	accepta

	cyclohexanol 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.	for CO_2 not reported. *See footnote for justification why this specification of carbon dioxide can be used in support of the carbon dioxide prescribed in this application.	677 cm^3 CO_2/litre cyclohexanol (at 26°C pressure 766 mmHg).	required for this data end point can be derived from existing data. The data provided about solubility in cyclohexanol has been sourced from data found in the public domain. Experimental determination of the cyclohexanol-solubility of the carbon dioxide prescribed in this application will not add any new information to the huge volume of phys-chem data available for carbon dioxide which is in broad agreement regarding the accepted cyclohexanol-solubility for carbon dioxide.			(1927)	ble
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)	N/A	N/A	N/A -	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	N/A	Not applicable. Reliability cannot be assigned because no experimental test data has been submitted	None.	accepta ble

				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 will be supplied as a 100% gas when it is marketed as a biocide. It does not contain any organic solvents, therefore stability data for carbon dioxide in organic solvents is not required.		to meet this data end point. This is because the study to determine the stability of carbon dioxide in organic solvents is not scientificall y necessary.		

3.9	**Partition coefficient n-octanol/water (IIA3.6)** log Pow 1	Not given.	Not given.	Partition Coefficient *K* for carbon dioxide at about 25°C: octanol and water: 0.83 Isobutanol and water: 2.26 Olive oil and water: 1.74	The partition coefficient provided has been sourced from data found in the public domain. Experimental determination of the partition coefficient of the carbon dioxide prescribed in this application will not add any new information to the huge volume of phys-chem data available for carbon dioxide which is in broad agreement regarding the accepted partition coefficient for carbon dioxide.	N	3	EPI Suite Battino R, Evans FD, Danforth WF, and Wilhelm E (1971)	acceptable
3.10	**Thermal stability, identity of relevant breakdown products (IIA3.7)**	Thermodynamic study–	The thermal stability of carbon dioxide, as determined theoretically by calculation in this study can be used to support the thermal stability of the carbon dioxide prescribed in	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	The thermal stability data provided has been sourced from data found in the public domain. Experimental determination of the thermal stability of the carbon dioxide prescribed in this application will not	N	Study conducted in accordance with generally accepted scientific principles, possibly with incomplete reporting	Greenwood NN and Earnshaw A (1984) Lietzke MH and Mullins C (1981)	acceptable

		this application because it is supplied as a 100% gas. There will be a few impurities present in the carbon dioxide which will be marketed as a biocide (and these are prescribed in this application), but these are present at such low levels that they are not believed to significantly effect the thermal stability of carbon dioxide.	wide range of temperature and pressure, carbon dioxide dissociates into carbon monoxide and oxygen with no precipitation of carbon. Thermodynamically, carbon dioxide is stable under atmospheric pressure up to approximately 300°C. Over this temperature, it dissociates in carbon monoxide and oxygen. At room temperature, CO2 is stable from 10^{-5} to 100 atm. CO2 <-> CO + 1/2 O2	add any new information to the huge volume of phys-chem data available for carbon dioxide which is in broad agreement regarding the accepted thermodynamics of carbon dioxide.		or methodological deficiencies, which do not affect the quality of relevant results. The information required for this data end point can be derived from existing data.		
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)	N/A	N/A	N/A	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	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	None.	acceptable

				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.		scientifically necessary to conduct a flammability and auto flammability test for carbon dioxide.		
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	N/A	0 : Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point.		acceptable

				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.				

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	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.	Method A.5 Surface Tension European Commission (1997) Classification, Packaging and Labelling of Dangerous Substances in the European Union. Part II - Testing Methods Page 51-57 Office for Official Publications of the European Communities ISBN 92-828-0076-8	acceptable

				risk assessment.				
3.14 Viscosity (-)	N/A	N/A	N/A	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	N/A	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.	acceptable

				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.				
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	N/A	0: Not applicable. Reliability cannot be assigned because no experimental test data has been submitted to meet this data end point.		acceptable

				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.				
3.16 Oxidizing 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	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		acceptable

				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.		oxidising properties is technically not possible to perform. This study is also not scientificall y necessary.		
3.17 Reactivity towards container material (IIA3.13)			Carbon dioxide is supplied in containers designed and manufactured in accordance with EN-ISO 9809-1:2010 (Gas ciliners - Rifillable seamless steel gas cylinders - Design, construction and testing - Part 1: Quenched and tempered steel cylinders with tensile strength less than 1100 MPa), and EN-ISO 9809-3:2010 (Gas cylinders - Refillable seamless steel gas cylinders - Design, construction and testing - Part 3: Normalized steel	The information required for this data end point can be derived from existing data. The storage stability of carbon dioxide can be confirmed as acceptable, even though there is no specific test data available, because the packaging used is in accordance with proven industry standards for carbon dioxide. Because of this, experimental determination of the storage stability of carbon	N	0 Reliability cannot be assigned because no experiment al test data has been submitted to meet this data end point. The information can be derived from existing data.	EN-ISO (2010a,b)	acceptable

		cylinders). Containers manufactured to this specification will ensure that there is no reactivity between the carbon dioxide and its container.	dioxide will not provide any useful information for the risk assessment.	

Official use only

JUSITIFCATION FOR NON SUBMISSION

1.1.1 **Analysis of the active substance as manufactured**

Quality standards for food grade carbon dioxide are set by the European Industrial Gases Association (EIGA) working in conjunction with the Compressed Gases Association of America (CGA) and the International Society of Beverage Technologists (ISBT). In these standards, the purity, the impurities to be analysed and the analytical methods are defined.

Carbon dioxide content is determined by absorption trapping in KOH while impurities are measured gravimetrically, or by spectroscopy (MS, IR, UV), atomic absorption and/or chemical analysis.

Formulation analysis

There is no formulation process involved for the use of carbon dioxide as avicide. Consequently, no separate information on a biocidal product is necessary.

Residue analysis

No methods for measurement of carbon dioxide residues in soil, air, water, body fluids/tissues, in/on food or feedstuff and other products are submitted.

- After use as avicide the carbon dioxide is released into the atmosphere. Here the gas is rapidly diluted and becomes part of the carbon dioxide pool present in the surrounding air.
- The amounts of carbon dioxide used as avicide are on a kilogramme scale which is negligible compared to the billions of tonnes of carbon dioxide which are released into the atmosphere following natural processes and human activities.

- In living organisms, carbon dioxide levels are well controlled.
- Free exchange of carbon dioxide in food or feedstuff and other products with the surrounding atmosphere can occur during production, preparation and consumption.
- Carbon dioxide is included in Annex IV of COMMISSION REGULATION (EC) 149/2008 (List of active substances of plant protection products evaluated under Directive 91/414/EEC for which no MRLs are required)

In conclusion, no methods are required to determine carbon dioxide in residues in soil, air, water, body fluids, food or other relevant products following its use as an avicide

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	March 2013
Materials and methods	Justification for non submission of data is considered acceptable.
Conclusion	The justification for the non submission of analytical methods for the active substance as manufactured as for the formulation are considered acceptable as there are methods available via public literature for carbon dioxide as a commonly available gas. Furthermore the formulation is identical to the active substance, therefore no anlaytcail methods for the formulation is required. No residue analytical methods are submitted to determine carbon dioxide in food and feed and the environmental matrices. This is considered acceptable as carbon dioxide is already present in large quantities in all matrices, therefore monitoring regarding this application is not required.
Reliability	
Acceptability	acceptable
Remarks	

Section A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	Avicide	
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)**	Nuisance birds	
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	Airplanes taking off and landing	
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 organisms (IIA5.3)**	Unconsciousness, minimal brain activity, ineffective heartbeat and ultimately death.	X
5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**	70-90 %v/v in air	
5.4	**Mode of action (including time delay) (IIA5.4)**		
5.4.1	**Mode of action**	The biocidal action of carbon dioxide is primarily due to it causing "respiratory acidosis" in target animals, leading to unconsciousness, minimal brain activity, ineffective heartbeat and ultimately death.	
5.4.2	**Time delay**	Unconsciousness is observed before target concentration (70-90 %v/v in air) is reached. Administration of carbon dioxide is regulated in such a way that the concentration is reached within 1 minute. Death (ineffective heart beat) is observed within 5 minutes. The sensitivity of geese, chickens, ducks and turkeys to increasing carbon dioxide concentrations was found to be very similar.	
5.5	**Field of use envisaged (IIA5.5)**		
	MG03: Pest control	PT15, avicide	
5.6	**User (IIA5.6)**		

Section A5		Effectiveness against target organisms and intended uses	
	Industrial	Industrial use as avicide is not envisaged	
	Professional	Carbon dioxide is used by professional pest control officers to kill nuisance birds.	
	General public	Non-professional use as avicide is not envisaged.	
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**	The biocidal action of carbon dioxide is primarily due to it causing "respiratory acidosis" in target animals. The development of resistance to carbon dioxide is not possible because, when used as a biocide, it will be lethal to the target birds in a single dose. Killing the target bird in a single dose means that no mechanism for resistance to carbon dioxide can be developed because target organisms are never exposed to sub-lethal concentrations of carbon dioxide (as a biocide).	X
5.7.2	**Management strategies**	Not applicable as resistance is not envisaged to develop.	
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	Not relevant because carbon dioxide is present in billions of tons in the earth's atmosphere and carbon dioxide is a HPV chemical which is used as food additive and in the production of in oil and chemicals. Only a small fraction is used as biocidal active substance.	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	9-4-2013
Comments	5.3.1: A study is provided in which activity of CO_2 against geese is shown. Summary of the study is shown in Table 5.3 below and Doc IIIB5. 5.7.1: The target organisms are during their life constantly exposed to sub-lethal concentrations of carbon dioxide in the air. However, during biocidal treatment it can be made sure that all birds treated are killed.
Conclusion	Applicant's version is adopted.

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*)
Avicide	PT15	≥ 99.7% pure carbon dioxide	Goose (*Anser anser*) / adult males and females/	Geese were instrumented for recording of EEG and ECG. Subsequently the animals were placed in an air tight container in which carbon dioxide was led.	The time to reach unconsciousness, minimal brain activity and ineffective heartbeat during anaesthesia and killing the geese of birds with carbon dioxide was measured. The animals were exposed to carbon dioxide concentrations between 70 and 90%. The concentration was reached within 1 minute after start of administration of the gas to the container in which the animals were placed.	The geese reached the stage of unconsciousness within one minute (56 seconds in CO_2) i.e. before the target concentration was reached. Minimal brain activity and ineffective heart rate were registered after 112 and 312 seconds respectively.	Wageningen UR Livestock Research (July 2010)

* References:

Wageningen UR Livestock Research (July 2010). Killing of wild geese with CO_2 and argon; Report 338a.

Section A6	HUMANTOXICOLOGICAL PROFILE	
	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]	

Section A6	HUMANTOXICOLOGICAL PROFILE	
Detailed justification:	A number of publicly available and published studies are summarised in Document II of the application dossier, but no Document III summaries are provided. These literature data were included for supporting purposes and are considered non-essential for the evaluation of carbon dioxide as an avicide (PT15) within the framework of the Biocidal Products Directive 98/8/EC for the reason given below. It is not technically possible to determine the toxicity of carbon dioxide – a gas – by the oral or dermal route, or to perform skin sensitisation or skin and eye irritation studies. The principle route of exposure to carbon dioxide will be inhalation, which should however be viewed in relation to the concentration of carbon dioxide in exhaled air of approximately 5%. Fully guideline-compliant acute or repeated dose toxicity studies for carbon dioxide by the inhalation route are not available. Nevertheless, there is a substantial volume of information on inhalation toxicity of carbon dioxide available, including data on humans. The available studies are considered as supportive data and as such are summarised in Document IIA3. Largely based on the same studies, an Occupational Exposure Limit (OEL) of 5,000 ppm (0.5% - 8-h time weighted average) was established in Directive 2006/15/EC in implementation of Directive 98/24/EC. For the specific case of CO_2, for which the human metabolism is well known, for the purpose of the risk assessment the OEL was preferred to the derivation of a reference concentration from NOAEL or LOAEL derived in the available animal studies of poor reliability. For the same reason, because the OEL was accepted at the EU level, non-submission of data is deemed acceptable and new testing is not considered necessary.	X

Section A6	HUMANTOXICOLOGICAL PROFILE
Undertaking of intended data submission [ ]	Not applicable
	COMMENTS FROM ...
Date	*13th of December 2013*
Comments on applicant's data	*Applicant's justification is acceptable.*
Conclusion	*Applicant's justification is acceptable.*
Acceptability	
Remarks	For the human health effects assessment of CO_2 for PT15 the relevant information and data available (open literature) already described in the Draft Assessment Report for Plant Protection Products (2009) and in the Competent Authority Report for PT14 (2006) are used.

Section A7	ECOTOXICOLOGICAL PROFILE INCLUDING ENVIRONMENTAL FATE AND BEHAVIOUR	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier. If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	Technically not feasible [ ] Scientifically unjustified [4] Other justification [ ]	

Section A7	ECOTOXICOLOGICAL PROFILE INCLUDING ENVIRONMENTAL FATE AND BEHAVIOUR
Detailed justification:	A number of publicly available and published studies are summarised in Document II of the application dossier, but no Document III summaries are provided. These literature data were included for supporting purposes and are considered non-essential for the evaluation of carbon dioxide as an avicide (PT15) within the framework of the Biocidal Products Directive 98/8/EC for the reason given below. Carbon dioxide is representing the end point in mineralisation of organic substances. Therefore it is not subject to biological degradation. Since it is a gas, carbon dioxide used as an avicide in confined spaces will rapidly enter the atmosphere when vented and contribution to naturally occurring carbon dioxide concentrations will be negligible. Testing for the biodegradability of carbon dioxide and testing for route and rate of degradation in soil or water is scientifically unjustified and therefore not applicable. During the 9th Technical Meeting in February 2003, it was agreed that environmental properties data are not required for CO2, and where relevant, could come from literature. Because of the rapid dilution of carbon dioxide in adjacent air (inhomogeneous concentration on a spatial and temporal scale) it is not reasonable to calculate PEC-values for environmental compartments for the use of carbon dioxide as an avicide (geese killing). It can be concluded that due to the high gradient in carbon dioxide concentration, when the gas is released to air, there will be a fast transport and dispersion of carbon dioxide in air preventing initial or time-weighted average concentrations that would be relevant with regard to ecotoxicological effects to the environment. Considering the vast amounts of carbon dioxide, naturally present in air, water and soil as part of the global carbon cycle, a measurable elevation of carbon dioxide concentrations in air, surface water or soil from its use as an avicide can be excluded. For algae, aquatic and terrestrial plants carbon dioxide is an essential substrate for photosynthesis and hence it is not scientifically necessary to calculate the growth inhibition caused by it. Regarding toxicity to fish, aquatic invertebrates and earthworms, available literature data of insufficient quality were not used in the risk assessment of carbon dioxide used as a biocide (PT14 and PT18) or as a plant protection product. It is proposed that, because of the lack of relevant exposure of the environmental compartments, there is no unacceptable risk for non-target organisms from the use of carbon dioxide as an avicide for the control of nuisance birds.

Section A7	ECOTOXICOLOGICAL PROFILE INCLUDING ENVIRONMENTAL FATE AND BEHAVIOUR	
Undertaking of intended data submission [ ]	Not applicable	