# HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

**BIJLAGE II** bij het besluit d.d. 1 mei 2015 tot toelating van het middel DUKE's Carbon Dioxide, toelatingnummer NL-0012083-0000

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

# RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION



DUKE's Carbon Dioxide

Product type 15

Carbon Dioxide

Case Number in R4BP: BC-MM01472L-40

**Evaluating Competent Authority: Netherlands** 

Date: May 1<sup>st</sup> 2015

### **Table of Contents**

1	CC	ONCLUSION	4
2	AS	SSESSMENT REPORT	5
	2.1	SUMMARY	5
	2.:		5
			5
			5
			5
		D. Hazard and precautionary statements	6
	2.:	1.1.2 Summary of the physical, chemical and technic	al properties7
	2.:	1.1.3 Summary of the Human Health Risk Assessmen	ıt9
	2.1	1.1.4 Summary of the Environmental Risk Assessmen	nt11
	2.2	GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION	
	2.2	.2.1 Administrative information	
		A. Trade name of the product	14
		B. Authorisation holder	14
			applicant14
			14
	2.2		
			osition of the biocidal product15
		**	
		· ·	
			oduct
		B. Particulars of likely direct or indirect effects, first aid in	
		environment	- · · · · · · · · · · · · · · · · · · ·
		C. Instructions for safe disposal of the product and its pa	ckaging18
		D. Conditions of storage and shelf-life of the product und	er normal conditions of storage18
	2.2	.2.6 Documentation	
		A. Data submitted in relation to product application	
			19
	2.3		
	2.3	,, , , , , , , , , , , , , , , , , , , ,	21
			21
		· · · · ·	r objects to be protected21
			ffering21
			21
		i. Occurrence of resistance and resistance management	

	G.	Known limitations	22
	Н.	Evaluation of the label claims	22
	I.	Relevant information if the product is intended to be authorised for use with other biocidal product(s)	22
	2.3.5	Risk assessment for human health	22
	A.	Assessment of effects on Human Health	22
	В.	Exposure assessment	25
	C.	Risk characterisation for human health	30
	2.3.6	Risk assessment for animal health	33
	2.3.7	Risk assessment for the environment	
	A.	Effects assessment on the environment	33
	В.	Exposure assessment	33
	C.	Risk characterisation	34
	2.3.8	Measures to protect man, animals and the environment	34
	A.	Recommended methods and precautions	34
	В.	Identity of relevant combustion products in cases of fire	35
	C.	Specific treatment in case of an accident	35
	D.	Possibility of destruction or decontamination following release	35
	E.	Procedures for waste management of the biocidal product and its packaging	35
	F.	Procedures for cleaning application equipment where relevant	
	G.	Specify any repellents or poison control measures included in the product	35
	2.3.9	Assessment of a combination of biocidal products	35
	2.3.10	Comparative assessment	36
3	ANNE	XES	37
•			
		IST OF STUDIES FOR THE BIOCIDAL PRODUCT	
	3.2	DUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS	37
	3.3	New Information on the active substance	37
	3.4 F	RESIDUE BEHAVIOUR	37
	3.5	SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-xx)	37
		CONFIDENTIAL ANNEX	

### 1 CONCLUSION

It is concluded that the application of DUKE's Carbon Dioxide according to the use instructions as stated in the SPC, will be effective and that there will be no harm for the health of humans and for the environment.

### 2 ASSESSMENT REPORT

### 2.1 SUMMARY

### 2.1.1 Presentation of the biocidal product

The biocidal product DUKE's Carbon Dioxide is identical to the active substance carbon dioxide (PT15), except for the use agains geese on agricultural land to prevent damage to the land. Carbon dioxide as active substance in avicides was approved by Commission implementing regulation (EU) 2015/292 of 24 February 2015.

DUKE's Carbon Dioxide is the reference product in the Assessment Report for carbon dioxide (PT15), finalized in the Biocidal Products Committee meeting on 17 June 2014. Therefore no new data/information is required.

### A. IDENTITY OF THE ACTIVE SUBSTANCE

Main constituent(s)		
ISO name	Carbon dioxide	
IUPAC or EC name	Carbon dioxide	
EC number	204-696-9	
CAS number	124-38-9	
Index number in Annex VI of CLP	-	
Minimum purity / content	99.9% v/v (food grade)	
Structural formula	0=C=0	

### **B. PRODUCT COMPOSITION AND FORMULATION**

# Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Carbon dioxide		Active substance	124-38-9	204-696-9	100

### Information on the substance(s) of concern

The product contains no substances of concern.

### C. INTENDED USE(S)

Table 1: Use # 1 - killing of captured wild geese

Product Type(s)	15
Where relevant, an exact description of the authorised use	Killing of captured wild geese
Target organism (including development stage)	Goose (Anser sp., Branta sp.), adult and juvenile, during moulting period
Field of use	Control of nuisance geese to protect - Airplanes taking off and landing - Agricultural crops
Application method(s)	Gas is released in a closed system
Application rate(s) and frequency	Geese are exposed to 70-90% carbon dioxide for 5 minutes in an air tight container. The carbon dioxide concentration in the container is monitored to ascertain that the required concentration of 70-90% carbon dioxide is reached within 1 minute and maintained for 5 minutes.
Category(ies) of user(s)	professional
Pack sizes and packaging material	10 - 50 L steel gas cylinder Cylinders which are used for food grade carbon dioxide are equipped with a dedicated valve (residual valve) to avoid contamination of the contents of the cylinder. Cylinders contain a blind nut and safety cap.

### D. HAZARD AND PRECAUTIONARY STATEMENTS

### Classification and Labelling according to Regulation (EC) No 1272/2008:

Classification	
Hazard category	Liquefied gas
Hazard statement	H280 – Contains gas under pressure; may explode if heated
Labelling	
Signal words	Warning
Hazard statements	H280 – Contains gas under pressure; may explode if heated
Precautionary	P403 – Store in a well-ventilated place
statements	
Note	EIGA-As. Asphyxiant in high concentrations

### Classification and Labelling according to the Directive 1999/45/EC:

Classification		Labelling		
Indications of R-phrases				S-phrases
danger		danger		
none	none	none	None	none

### E. PACKAGING OF THE BIOCIDAL PRODUCT

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non- professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Gas cylinder	10 - 50 L	steel	Dedicated valve (residual valve) to avoid contamination of the contents of the cylinder	Professional	yes

### 2.1.2 Summary of the physical, chemical and technical properties

The biocidal product is identical to the active substance,  $\geq$  99.9% (v/v) carbon dioxide. The applicant is also notifier of the Assessment Report for carbon dioxide (PT15), finalised in the Biocidal Products Committee meeting on 17 June 2014, in which the physicochemical properties of the active substance are detailed.

Carbon dioxide is one of the end products of the breakdown of carbon containing materials. No further degradation of carbon dioxide takes place under ambient temperature and pressure. For this reason the manufacturer, Linde Gas Benelux, guarantees a shelf life of five years.

For full details on the manufacturer(s), please refer to the CA-report or the SPC.

### Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	Carbon dioxide
Product-type	PT 15
Applicant	Duke Faunabeheer
Manufacturer of Active Substance	Linde Gas Benelux
Manufacturer of Product(s)	Linde Gas Benelux
Identity	
Chemical name (IUPAC)	Carbon dioxide
Chemical name (CA)	Carbon dioxide
CAS No	124-38-9

EC No	204-696-9
Other substance No.	None known
Minimum purity of the active substance as manufactured (g/kg or g/l)	99.9% v/v
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	CO <sub>2</sub>
Molecular mass	44.01 g/mol
Structural formula	O=C=O
Physical and chemical properties	
Melting point (state purity)	-78.5°C, sublimation point
Boiling point (state purity)	-78.5°C, sublimation point
Temperature of decomposition	> 300°C
Appearance (state purity)	odourless, colourless gas
Relative density (state purity)	1.527 (where air = $1$ ).
Surface tension	n.a.
Vapour pressure (in Pa, state temperature)	n.a.
Henry's law constant (Pa m³mol <sup>-1</sup> )	n.a.
Solubility in water (g/l or mg/l, state temperature)	1.50 g/kg (25°C; partial pressure of gas: 101.325 kPa)
Solubility in organic solvents (in g/l or mg/l, state temperature)	Soluble in ethanol, acetone, ethylene glycol, cyclohexanol
Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable. No organic solvents are used in the manufacture of carbon dioxide and no organic solvent is involved in the integration of carbon dioxide in Duke's Carbon Dioxide.
Partition coefficient (log $P_{\text{OW}}$ ) (state temperature)	n-octanol/water: 0.83 (measured)
	Isobutanol/water: 2.26
	Olive oil/water: 1.74
Hydrolytic stability ( $DT_{50}$ ) (state pH and temperature)	Dissolved carbon dioxide will react with water to form carbonic acid.
	$CO_2 + H_2O \leftrightarrow H_2CO_3$ Carbonic acid will undergo further reactions to produce bicarbonate and carbonate ions. $H_2CO_3 + OH^- \leftrightarrow HCO_3^- + H_2O$ $HCO_3^- + OH^- \leftrightarrow CO_3^{2-} + H_2O$

	The equilibrium constant for the disassociation reaction is 600. Carbon dioxide is considered to be hydrolytically stable.
Dissociation constant	n.a.
UV/VIS absorption (max.) (if absorption > 290 nm state $\epsilon$ at wavelength)	n.a.
Photostability ( $DT_{50}$ ) (aqueous, sunlight, state pH)	n.a.
Quantum yield of direct phototransformation in water at S> 290 nm	n.a.
Flammability	n.a.
Explosive properties	n.a.
Classification and proposed labelling	
with regard to physical/chemical data	Not classified as hazardous
with regard to toxicological data	Not classified as hazardous
with regard to fate and behaviour data	Not classified as hazardous
with regard to ecotoxicological data	Not classified as hazardous

### 2.1.3 Summary of the Human Health Risk Assessment

The biocidal product is identical to the active substance,  $\geq$  99.9% (v/v) carbon dioxide. The applicant is also notifier of the Annex I dossier for carbon dioxide PT15, in which the toxicological properties of the active substance are described in detail.

Endpoint	Brief description
Skin corrosion and irritation	It is technically not possible to perform irritation studies to eye or skin and to perform a skin sensitisation study because carbon dioxide is a gas. Therefore, it is considered not necessary to require these studies. Additionally, it should be noted, that there is no evidence for skin / eye irritation or skin sensitisation by carbon dioxide, so far.
Eye irritation	See above
Skin sensitisation	See above
Respiratory sensitization (ADS)	Studies of the response of the body to increased carbon dioxide concentrations were performed. There was no evidence of respiratory sensitisation by carbon dioxide.
Acute toxicity by oral route	As carbon dioxide is a gas, oral exposure will not be a significant route of exposure.
Acute toxicity by inhalation	Studies of the response of the body to increased carbon dioxide concentrations showed that at 2% carbon dioxide the body adapts, 9% was tolerated for at least 12 minutes, and that 10.6%

	carbon dioxide was experienced as very unpleasant by human volunteers.
Dermal absorption	As carbon dioxide is a gas, dermal exposure will not be a significant route of exposure.
Other effects	None known
Available toxicological data relating to non active substance(s)	The biocidal product is identical to the active substance and contains no non-active substances
Available toxicological data relating to a mixture	Not applicable, the product is not mixed.
Other relevant information	Carbon dioxide is constantly produced by the body as a result of the numerous metabolic reactions involving carbon-containing compounds. An adult man, at rest, can be expected to contribute approximately 12 litres of carbon dioxide per hour to his blood stream. If undergoing sustained work, carbon dioxide production can increase to around 100 litres of carbon dioxide per hour. The body has an ability to excrete carbon dioxide in amounts which correspond to over 12,000 mEq of acid per day without causing any toxic effects.

#### Reference values

A number of regulatory authorities has set national, international and supranational maximum exposure limits for safe working conditions (e.g. Commission Directive 2006/15/EC; in UK: Health and Safety Executive, 2011; Germany: DFG/MAK, 1983, 2002, and TRGS 900). All of these exposure limits are in general agreement: TWA 8 hrs of 0.5% (5000 ppm) and TWA 15 mins of 1.5% (15000 ppm).

#### Risk characterisation

### Professional users

Exposure of professional users to carbon dioxide during its use as avicide is considered to be negligible. Killing of large numbers of geese takes place 2 to 4 times per day during a maximum of 8 weeks per year. Emptying and/or re-entry of the container which is used for killing of geese takes place after the carbon dioxide has dropped to levels below occupational exposure limits in the safe working conditions (TWA 8 h: 5000 ppm = 0.5%). In rare cases when the professional user will need to enter the container room when the concentration of carbon dioxide is above 1.5%, PPE such as self-contained breathing apparatus (SCBA) should be used. The duration of the exposure during the incidental reentry of the container by professional users is not expected to exceed 15 minutes, therefore it is considered appropriate to compare the exposure levels with the short-term TWA 15 min of 1.5 %. For further personal protection a portable carbon dioxide detector, which gives an alerting signal when the carbon dioxide concentration exceeds safe levels (0.5%), is used when entering the container room shortly after use for killing of geese.

The safety limits for carbon dioxide (TWA 8 h of 0.5% (5000 ppm) and TWA 15 min of 1.5% (15000 ppm)) have resulted from a thorough evaluation of the properties of carbon dioxide by a number of regulatory authorities to set national, international and supranational maximum exposure limits for safe working conditions, and all of these

exposure limits are in general agreement. Therefore no concern for adverse effects from exposure to carbon dioxide due to its application as an avicide exists for professional user if exposure concentrations remain under the safety limits, and no further risk assessment has been performed for the professional use as an avicide.

It can be concluded that by using the following safety measures:

- 1: proper venting of the container used for killing of geese
- 2: monitoring of the carbon dioxide concentration
- 3: re-entry of the container after the carbon dioxide has dropped to levels below occupational exposure limits in the safe working conditions (TWA 8 h: 5000 ppm = 0.5%) 4: use of a self-contained breathing apparatus (SCBA) in case the limit value of 1.5% (TWA 15 min) is exceeded),

the exposure of professional users to carbon dioxide when it is used as avicide is considered to be negligible.

### Non-professional users

As the gassing will only be performed by professionals, no exposure of non-professional users will occur.

### Indirect (secondary) exposure

Bystanders might be exposed to carbon dioxide when used as avicide. However, since application of carbon dioxide does not result in exposure of professional users above safe working limits, the exposure of bystanders in a worst case situation is also considered not to exceed these safe limits.

Geese which were killed with carbon dioxide might be used for human consumption or might be processed for use in animal feed production. However, as carbon dioxide is a gas, during processing free exchange of the carbon dioxide with the surrounding atmosphere occurs. The exposure to significant levels of carbon dioxide following consumption of geese killed with carbon dioxide is considered negligible.

Application of carbon dioxide as avicide does not result in residues to which consumers might become exposed. The carbon dioxide which is used as avicide is food grade and does not contain impurities which can form a concern with respect to indirect exposure by food.

In proportion to the tonnage of carbon dioxide as part of the global carbon cycle, indirect exposure of the general public following the use of carbon dioxide as avicide is considered negligible.

### 2.1.4 Summary of the Environmental Risk Assessment

For the product DUKE's Carbon Dioxide no new studies have been provided. DUKE's Carbon Dioxide is the reference product in the Assessment Report for carbon dioxide (PT15) and therefore no new data/information is required.

Detailed data on the fate and distribution of carbon dioxide in the environment and the effect of the active substance on environmental organisms can be consulted in Doc IIA of the AR for carbon dioxide (PT15).

### Fate and behaviour in the environment

After being used as an avicide the carbon dioxide is released into the atmosphere where it mixes with the carbon dioxide already present. Carbon dioxide is a natural product of respiration in plants and animals and of combustion. The contribution from its use as an avicide to naturally occurring carbon dioxide concentrations will be negligible.

#### Effects assessment

No ecotoxicological studies have been submitted since no additional risk for the environment is anticipated for the proposed use of carbon dioxide as an avicide.

Due to the particular nature of carbon dioxide, it has to be considered that carbon dioxide does not fulfil persistence criteria in any environmental criteria and has no bioaccumulation potential. Carbon dioxide has no PBT potential. In addition, carbon dioxide is not classified as hazardous to health according to EC Directive 67/548/EEC, nor are there any indications of toxicity such as endocrine disruption. The toxicity profile of carbon dioxide, coupled with the fact that it is unlikely to accumulate in the environment, means that there is a low risk of primary and secondary poisoning of birds and mammals. Geese killed with carbon dioxide are not disposed of in the environment, but processed for food and feed consumption or otherwise destroyed.

### Exposure assessment

There will be no exposure of the aquatic environment to carbon dioxide. Consequently, adverse effects to aquatic organisms and sediment dwelling organisms from the use of carbon dioxide in avicide products do not need to be considered. Carbon dioxide will not enter sewage treatment plants and effects on micro-organisms in sewage treatment plants do therefore not need to be considered either. Similarly for the terrestrial and atmospheric environmental compartments, there will be no increase in the levels of carbon dioxide in the atmosphere or soil outside normal atmospheric ranges from the use of carbon dioxide as an avicide.

In the Assessment Report for carbon dioxide (PT15), the PEC was set to zero for all the compartments, meaning that the use of carbon dioxide as a biocide (avicide) will not increase carbon dioxide concentrations outside natural ranges.

### Risk characterization

Given the effectively zero level of exposure expected in all environmental compartments from the use of carbon dioxide as an avicide, it was concluded in the Assessment Report that there is no risk to the environment or wildlife. Please notice that the removal/killing of geese from areas may influence the environment and wildlife. For this reason, the use of DUKE's Carbon Dioxide is subject to permission by the competent authority for the Law on flora and fauna (Flora- en Faunawet).

### Conclusion:

Application of carbon dioxide as avicide does not result in a risk to the environment or wildlife. It is not expected that released carbon dioxide increases the concentrations in the

atmosphere significantly as the emission from the application of carbon dioxide as avicide compared to natural emission sources is negligble.

### 2.2 GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION

### 2.2.1 Administrative information

### A. TRADE NAME OF THE PRODUCT

Trade name	Country (if relevant)
DUKE's Carbon Dioxide	The Netherlands

### **B. AUTHORISATION HOLDER**

Name and address of the	Name	Duke Faunabeheer
authorisation holder		Schoepenweg 24 8243 PX Lelystad The Netherlands
Telephone:	+31 320 219500	
Fax:	+31 320 219777	
E-mail address:	dwdenhertog@dukefaunabeheer.nl	
Case number in R4BP3:	BC-MM01472L-40	

# C. PERSON AUTHORISED FOR COMMUNICATION ON BEHALF OF THE APPLICANT

Name:	D.W. den Hertog
Function:	Director
Address:	Schoepenweg 24
City:	Lelystad
Postal Code:	8243 PX
Country:	The Netherlands
Telephone:	+31 320 219500
Fax:	+31 320 219777
E-mail address:	dwdenhertog@dukefaunabeheer.nl

### D. MANUFACTURER(S) OF THE PRODUCT

Name of manufacturer	Linde Gas Benelux
	Havenstraat 1 3115 HC Schiedam The Netherlands
Location of manufacturing sites	As above

### E. CANDIDATE(S) FOR SUBSTITUTION

Carbon dioxide is not a candidate for substitution.

### 2.2.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes	$\boxtimes$
No	

### A. IDENTITY OF THE ACTIVE SUBSTANCE

Main constituent(s)			
ISO name	Carbon dioxide		
IUPAC or EC name	Carbon dioxide		
EC number	204-696-9		
CAS number	124-38-9		
Index number in Annex VI of CLP	-		
Minimum purity / content	99.9% v/v (food grade)		
Structural formula	O=C=O		

# B. QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION OF THE BIOCIDAL PRODUCT

99.9% v/v carbon dioxide (food grade). Please see the confidential annex for further details.

### C. INFORMATION ON TECHNICAL EQUIVALENCE

Not relevant.

### D. INFORMATION ON THE SUBSTANCE(S) OF CONCERN

The biocidal product contains no substances of concern.

### E. TYPE OF FORMULATION

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### 2.2.3 Intended use(s)

Table 1: Use # 1 - killing of captured wild geese

Product Type	15
Where relevant, an exact description of the authorised use	Killing of captured wild geese
Target organism (including development stage)	Goose (Anser sp., Branta sp.), adult and juvenile, during moulting period
Field of use	Control of nuisance geese to protect - Airplanes taking off and landing - Agricultural crops
Application method(s)	Gas is released in a closed system
Application rate(s) and frequency	Geese are exposed to 70-90% carbon dioxide for 5 minutes in an air tight container. The carbon dioxide concentration in the container is monitored to ascertain that the required concentration of 70-90% carbon dioxide is reached within 1 minute and maintained for 5 minutes.
Category(ies) of users	Professional
Pack sizes and packaging material	10 - 50 L steel gas cylinder Cylinders which are used for food grade carbon dioxide are equipped with a dedicated valve (residual valve) to avoid contamination of the contents of the cylinder. Cylinders contain a blind nut and safety cap.
Potential for release into the environment (yes/no)	yes (no increase of background)
Potential for contamination of food/feedingstuff (yes/no)	No

### 2.2.4 Hazard and precautionary statements

# A. PROPOSED CLASSIFICATION AND LABELLING OF THE BIOCIDAL PRODUCT

Classification and Labelling according to Regulation (EC) No 1272/2008:

Classification	
Hazard category	Liquefied gas
Hazard statement	H280 – Contains gas under pressure; may explode if heated

Labelling	
Signal words	Warning
Hazard statements	H280 – Contains gas under pressure; may explode if heated
Precautionary	P403 –Store in a well-ventilated place
statements	
Note	EIGA-As. Asphyxiant in high concentrations

### B. PACKAGING OF THE BIOCIDAL PRODUCT

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non- professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Gas cylinder	10 - 50 L	steel	Dedicated valve (residual valve) to avoid contamination of the contents of the cylinder	Professional	yes

### 2.2.5 Directions for use

#### A. INSTRUCTIONS FOR USE

### Use # 1 - killing of captured wild geese

### Manner and area of use

Geese, captured during the period of moulting, are placed in an air tight container. The carbon dioxide gas is led from one or more gas cylinders into the container to a concentration of 70-90% carbon dioxide. The gas concentration in the container is online monitored by means of a carbon dioxide meter. The geese are kept in the container for at least 5 minutes.

#### Conditions of use

To obtain sufficient efficacy, without unnecessary pain and suffering to the geese, the following conditions for use are set:

- the carbon dioxide flow into the container should be of such volume that the required concentration of 70-90% carbon dioxide is reached within 1 minute
- this concentration should be kept for at least 5 minutes
- to ensure these conditions are reached, the gas concentration in the container should

be (on-line) monitored by means of a carbon dioxide meter

The administration of the gas should be set at such a rate that the target concentration 70 to 90 % (v/v) is reached in maximum 1 minute.

PT15

This can be achieved by:

- 1. a constant flow rate and adjustment of the size of the gassing chamber, for example compartmentalisation, based on the number of geese to be killed.
- 2. a constant volume of the gassing chamber and adjustment of the flow rate based on the number of geese to be killed.

Settings of the flow rate should be determined during real-life test runs.

Use Restrictions:	carbon dioxide shall be used as a measure of last resort, in the context of an integrated pest management strategy, whose aim shall be to limit to the minimum the recourse to such a
	product

# B. PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

Carbon dioxide is a gas which may cause suffocation when present in high concentrations. Possible symptoms are: loss of the moving ability or unconsciousness. The victim is not aware of the suffocation. Exposure to low concentrations of carbon dioxide may cause accelerated breathing rate and headaches. Remove the victim to the non-polluted area and use independent breathing protection. Keep the victim calm and warm. Warn a doctor. Apply artificial insufflation if the victim stops breathing.

# C. INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

N	o	n	e
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# D. CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE

Store gas cylinders at ambient temperature and protected from direct sunlight. Shelf life: 5 years in steel gas cylinders

### 2.2.6 Documentation

### A. DATA SUBMITTED IN RELATION TO PRODUCT APPLICATION

No new data/information is submitted in relation to the application for approval of DUKE's Carbon Dioxide. The biocidal product DUKE's Carbon Dioxide is identical to the active substance carbon dioxide (PT15). Carbon dioxide as active substance in avicides was approved by Commission implementing regulation (EU) 2015/292 of 24 February 2015.

PT15

DUKE's Carbon Dioxide is the reference product in the Assessment Report for carbon dioxide (PT15), finalised in the Biocidal Products Committee meeting on 17 June 2014.

### **B. ACCESS TO DOCUMENTATION**

A letter of access is not required. The applicant is also the notifier of carbon dioxide as active substance in avicides (PT15).

### C. SIMILAR CONDITIONS OF USE

Not applicable.

### 2.3 ASSESSMENT OF THE BIOCIDAL PRODUCT

### 2.3.1 Physical, chemical and technical properties

The applicant is also the notifier of the active substance carbon dioxide (PT15). The physico/chemical properties for the active substance carbon dioxide are detailed in the Assessment Report for carbon dioxide (PT15), finalised in the Biocidal Products Committee meeting on 17 June 2014.

Since the active substance and the product are identical, no data are given here. See section 2.1.2.

Carbon dioxide is one of the end products of the breakdown of carbon containing materials. No further degradation of carbon dioxide takes place under ambient temperature and pressure. For this reason Linde Gas Benelux guarantees a shelf life of five years in steel gas cylinders.

### 2.3.2 Physical hazards and respective characteristics

Please refer to the active substance data for the product as they are identical. Carbon dioxide is a liquefied gas, supplied in steel cylinders. The product has a shelf-life of at least 5 years.

### 2.3.3 Methods for detection and identification

The applicant is also the notifier of the active substance carbon dioxide (PT15). Since the active substance and the product are identical, the evaluation of the analytical methods in the Assessment Report for carbon dioxide (PT15), finalised in the Biocidal Products Committee meeting on 17 June 2014, is referred to here.

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.

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. Justification for non submission for the relevant matrices:

- 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 residue analytical 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.

### 2.3.4 Efficacy against target organisms

### A. FUNCTION AND FIELD OF USE

The product DUKE's Carbon Dioxide is used by professional pest control officers for killing captured nuisance geese at and around airports and agricultural areas. This use is included in PT15.

# B. ORGANISMS TO BE CONTROLLED AND PRODUCTS, ORGANISMS OR OBJECTS TO BE PROTECTED

The organisms to be controlled are adult and juvenile geese (*Anser* sp., *Branta* sp.) that endanger public safety and health at and around airports or cause damage to agricultural crops. Objects to be protected are airplanes taking off or landing (the aim is to reduce the chance of collision between geese and airplanes) and agricultural crops.

# C. EFFECTS ON TARGET ORGANISMS, INCLUDING UNACCEPTABLE SUFFERING

The target organisms are killed. To prevent unnecessary suffering of the animals, the required concentration of 70-90% carbon dioxide is reached within one minute, and kept at that level for at least 5 minutes.

### D. MODE OF ACTION, INCLUDING TIME DELAY

The effectiveness of carbon dioxide is based on the fact that it displaces oxygen in the inhaled air, as a result of which a very low oxygenation of the blood is induced (hypoxemia). The mode of action of carbon dioxide is primarily due to it causing "respiratory acidosis", leading to unconsciousness, minimal brain activity, ineffective heartbeat and ultimately death. Unconsciousness is observed in geese before the target concentration (70-90% v/v in air) is reached.

#### E. EFFICACY DATA

No new data were submitted for the product, since it is identical to the reference product evaluated in the Assessment Report of carbon dioxide for PT15, finalised in the Biocidal Products Committee meeting on 17 June 2014.

In its application as an avicide, a sufficient degree of efficacy was demonstrated in geese. The test demonstrated 100% mortality of geese when exposed to carbon dioxide for 5 minutes in an air tight container. The carbon dioxide in the gassing container reached the

target concentration of >70% within 1 minute. Geese reached the stage of unconsciousness within one minute.

### **Conclusion on the efficacy of the product**

If used in accordance with the instructions of use, DUKE's Carbon Dioxide is sufficiently active as an avicide against geese.

### F. OCCURRENCE OF RESISTANCE AND RESISTANCE MANAGEMENT

The development of resistance to carbon dioxide is not to be expected. During biocidal treatment it can be made sure that all geese treated are exposed to a lethal dose and killed. Killing the target geese in a single dose means that no mechanism for resistance to carbon dioxide can be developed.

#### G. KNOWN LIMITATIONS

Precautions should be taken to avoid freezing of the tubing due to expansion of the gas.

### H. EVALUATION OF THE LABEL CLAIMS

The following conditions for use are added to the label to obtain sufficient efficacy, without unnecessary pain and suffering of the geese:

- the carbon dioxide flow into the container should be of such volume that the required concentration of 70-90% in air is reached within 1 minute
- this concentration should be maintained for at least 5 minutes
- to make sure these conditions are reached:
  - the gas concentration in the container should be (on-line) monitored by means of a carbon dioxide meter
  - settings of the flow rate should be determined before starting the control of geese, during real-life test runs
- precautions should be taken to avoid freezing of the tubing due to expansion of the gas.
- the product should be used as part of an Integrated Pest Management (IPM) strategy.

# I. RELEVANT INFORMATION IF THE PRODUCT IS INTENDED TO BE AUTHORISED FOR USE WITH OTHER BIOCIDAL PRODUCT(S)

Not relevant. The biocidal product is not used in combination with other products.

### 2.3.5 Risk assessment for human health

DUKE's Carbon Dioxide is the reference product in the Assesssment Report for carbon dioxide (PT15), finalised in the Biocidal Products Committee meeting on 17 June 2014. Therefore no new data/information is required.

The biocidal product is also identical to the active substance,  $\geq$  99.9% (v/v) carbon dioxide. The information presented below is copied from the Assessment Report.

### A. ASSESSMENT OF EFFECTS ON HUMAN HEALTH

#### Skin corrosion and irritation

Data waiving					
Information	7.3.1 Skin corrosion and irritation				
requirement					
Justification	It is technically not possible to perform irritation studies to eye or skin and to perform a skin sensitisation study because carbon dioxide is a gas. Therefore, it is considered not necessary to require these studies. Additionally, it should be noted, that there is no evidence for skin / eye irritation or skin sensitisation by carbon dioxide, so far.				

### Eye irritation

Data waiving	
Information	7.3.2 Eye irritation
requirement	
Justification	It is technically not possible to perform irritation studies to eye or skin and to perform a skin sensitisation study because carbon dioxide is a gas. Therefore, it is considered not necessary to require these studies. Additionally, it should be noted, that there is no evidence for skin / eye irritation or skin sensitisation by carbon dioxide, so far.

### Respiratory tract irritation

Data waiving	
Information	Respiratory tract irritation
requirement	
Justification	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%. National, international and supranational maximum exposure limits for safe working conditions for carbon dioxide are TWA 8 hrs of 0.5% (5000 ppm) and TWA 15 mins of 1.5% (15000 ppm). These levels are below the concentration in expired air. Therefore, it is considered not necessary to require a respiratory tract irritation study.

### Skin sensitization

Data waiving	
Information	7.4 Skin sensitization
requirement	
Justification	It is technically not possible to perform irritation studies to eye or skin and to perform a skin sensitisation study because carbon dioxide is a gas. Therefore, it is considered not necessary to require these studies. Additionally, it should be noted, that there is no evidence for skin / eye irritation or skin sensitisation by carbon dioxide, so far.

### Respiratory sensitization (ADS)

Data waiving	
Information requirement	7.4.2 Respiratory sensitization
Justification	Studies of the response of the body to increased carbon dioxide concentrations were performed. There was no evidence of respiratory sensitisation by carbon dioxide. Therefore, it is considered not necessary to require this study.

### Acute toxicity

### Acute toxicity by oral route

Data waiving	
Information	7.2.1 Acute oral toxicity
requirement	
Justification	It is not technically possible to determine the toxicity of carbon dioxide by the oral route. Furthermore, as carbon dioxide is a gas, oral exposure will not be a significant route of exposure. Therefore, it is
	considered not necessary to require this study.

### Acute toxicity by inhalation

Data waiving	
Information requirement	7.2.2 Acute inhalation toxicity
Justification	Available non-guideline studies (included in the dossier for the active substance) in human volunteers exposed to increased carbon dioxide concentrations in air, reveal that the body adapts to 2% carbon dioxide, that it tolerates 9% for at least 12 minutes, and that 10.6% carbon dioxide was experienced as very unpleasant. 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. Therefore, it is considered not necessary to require this study.

### Acute toxicity by dermal route

Data waiving	
Information	7.2.3 Acute dermal toxicity
requirement	
Justification	It is not technically possible to determine the toxicity of carbon dioxide by the dermal route. Furthermore, as carbon dioxide is a gas, dermal exposure will not be a significant route of exposure. Therefore, it is considered not necessary to require this study.

### Information on dermal absorption

Data waiving	
Information	7.1.2 Dermal absorption
requirement	
Justification	It is not technically possible to determine the dermal absorption of carbon dioxide. Furthermore, as carbon dioxide is a gas, dermal exposure will not be a significant route of exposure. Therefore, it is considered not necessary to require this study.

# Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

The biocidal product is identical to the active substance and contains no non-active substances.

### Available toxicological data relating to a mixture

Not relevant. The biocidal product and the active substance are the same.

#### Other

In food or feedstuff and other products, a free exchange of carbon dioxide with the surrounding atmosphere will occur during production, preparation and consumption. Therefore, exposure of geese to carbon dioxide as a result of the use of the biocidal product will not lead to increased concentrations in food or feed products prepared from the killed animals.

### **B. EXPOSURE ASSESSMENT**

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
	Primary (direct) exposure			Secondary (indirect) exposure			
Exposure path	Industrial use	Professional use	Non- professional use	Industrial use	Bystander	General public	Via food
Inhalation	n.a.	yes	n.a.	n.a.	yes	yes	no
Dermal	n.a.	no	n.a.	n.a.	no	no	no
Oral	n.a.	no	n.a.	n.a.	no	no	no

### List of scenarios

Summary table: scenarios						
Scenario number	Scenario (e.g. mixing/ loading)	Primary or secondary exposure Description of scenario	Exposed group (e.g. professionals, non- professionals, bystanders)			
1a.	Use of the biocidal product	Primary exposure: Prior to the use of DUKE's Carbon Dioxide captured geese are placed in an air tight container. The carbon dioxide gas is led from one or more gas cylinders into the container to a concentration of 70-90% v/v. The gas concentration in the container is on-line monitored by means of a carbon dioxide meter. The geese are kept in the container for at least 5 minutes before proper venting of the container. After death of the geese, the container is opened and carbon dioxide is released into the atmosphere. If the container is placed in a closed facility, the volume of the facility should be at least 50 times the volume of the container to allow for a sufficient dilution of carbon dioxide levels.  The re-entry of the container to remove dead geese is allowed only after the concentration of carbon dioxide has decreased below the long-term safe exposure level (TWA 8 hrs) of 0.5% (5000 ppm). If the container or a facility in which it is located need to be re-entered shortly after the use, the measurement of carbon dioxide concentration using a carbon dioxide meter needs to be conducted prior to the re-entry. If the concentration of carbon dioxide in the container exceeds the short-term safe exposure level (TWA 15 mins) of 1.5% (15000 ppm), personal protective equipment, such as self-contained breathing apparatus (SCBA) is prescribed for professional users.	professionals			
1b.		Primary exposure: Bystanders might be exposed to carbon dioxide when it is used as avicide. However, since application of carbon dioxide does not result in exposure of professional users above safe working limits, the exposure of bystanders in a worst case situation is also considered not to exceed these safe limits.	bystanders			
2.		Secondary exposure: In proportion to the tonnage of carbon dioxide as part of the global carbon cycle (EIGA, 2003), indirect exposure of the general public following the use of carbon dioxide as avicide is considered negligible.	general public			

### Industrial exposure

Not applicable.

### Professional exposure

The killing of geese takes place in an air-tight container, which is filled with carbon dioxide from an aerosol canister. Killing of large numbers of geese takes place 2 to 4 times per day during a maximum of 8 weeks per year. The concentration of carbon dioxide in the container is monitored by a carbon dioxide meter placed on the outside of the container. Therefore no exposure of professional users is expected to occur during the filling of the container and during the actual process of geese gassing. Exposure of professional users may occur only during the venting of the container and/or its re-entry after the geese have been killed.

Using the appropriate air monitoring equipment, professional users are expected to be exposed to negligible amounts of carbon dioxide during emptying and/or re-entry of the container used for killing geese after the concentration of carbon dioxide has dropped to safe levels. Removal of the killed animals from the container is only allowed after the carbon dioxide concentration in the container has dropped below the long-term occupational exposure limit (0.5% or 5000 ppm, 8-hour time weighted average). The time required to attain carbon dioxide concentrations of 0.5% was estimated to be 40 seconds (Duke Faunabeheer BV, 2012b, report in active substance file).

Occasionally, the professional user will need to enter the container room shortly after the use. In such cases the measurement of the carbon dioxide concentration using a carbon dioxide meter needs to be performed prior to the re-entry. If the concentration of carbon dioxide in the container is above the TWA 15 mins of 1.5%, PPE such as self-contained breathing apparatus (SCBA) is prescribed for professional users. The time required to attain a carbon dioxide concentration of 1.5% was estimated to be 32 seconds (Duke Faunabeheer BV, 2012b, report in active substance file).

For further personal protection the use of a portable carbon dioxide detector, which gives an alerting signal when carbon dioxide concentrations exceed safe levels, is recommended when re-entering the container. During actual gassing of geese, no carbon dioxide concentrations above the short-term occupational exposure limit (TWA 15 mins of 1.5%, or 15000 ppm) were detected by the portable carbon dioxide monitor at any time after opening the gassing chamber (Duke Faunabeheer BV, 2012b, report in active substance file).

### Non-professional exposure

Bystanders might be exposed to carbon dioxide when it is used as avicide. However, since application of carbon dioxide does not result in exposure of professional users above safe working limits, the exposure of bystanders in a worst case situation is also considered not to exceed these safe limits.

### Exposure of the general public

In proportion to the tonnage of carbon dioxide as part of the global carbon cycle (EIGA, 2003, report in active substance file), indirect exposure of the general public following the use of carbon dioxide as avicide is considered negligible.

### Monitoring data

No monitoring studies are available.

### Dietary exposure

Geese which were killed with carbon dioxide might be used for human consumption or might be processed for use in animal feed production. However, as carbon dioxide is a gas, during processing free exchange of the carbon dioxide with the surrounding atmosphere occurs. The exposure to significant levels of carbon dioxide following consumption of geese killed with carbon dioxide is considered negligible.

Application of carbon dioxide as avicide does not result in residues to which consumers might become exposed. The carbon dioxide which is used as avicide is food grade and does not contain impurities which can form a concern with respect to indirect exposure by food.

### Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses				
	Sector of use <sup>1</sup>	Intended use	Reference value(s) <sup>2</sup>	
1.	Food and beverage industry	Carbonation of drinks	-	
2.	Plant protection	Insecticide, rodenticide	No MRL required (included in Annex IV of COMMISSION REGULATION (EC) 149/2008)	

<sup>&</sup>lt;sup>1</sup> e.g. plant protection products, veterinary use, food or feed additives

### Estimating Livestock Exposure to Active Substances used in Biocidal Products

Exposure of livestock to carbon dioxide as a result of the use of the biocidal product is estimated to be negligible in comparison to the exposure from other sources. 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.

<sup>&</sup>lt;sup>2</sup> e.g. MRLs. Use footnotes for references.

# <u>Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)</u>

### Scenario 1

Geese which were killed with carbon dioxide might be used for human consumption or might be processed for use in animal feed production. However, as carbon dioxide is a gas, during processing free exchange of the carbon dioxide with the surrounding atmosphere will occur. The exposure to significant levels of carbon dioxide following consumption of geese killed with carbon dioxide is considered negligible.

#### **Conclusion**

Application of carbon dioxide as avicide does not result in residues to which consumers might become exposed.

# Exposure associated with production, formulation and disposal of the biocidal product

The biocidal product is identical to the active substance and is supplied in ready for use gas cylinders. Empty gas cylinders are returned to the manufacturer.

### Aggregated exposure

Not relevant.

### Summary of exposure assessment

Scenarios and values to be used in risk assessment					
Scenario number	Exposed group (e.g. professionals, non- professionals, bystanders)	Tier/PPE	Estimated total uptake		
1.	professionals	-	negligible		
2.	bystanders	-	negligible		

### C. RISK CHARACTERISATION FOR HUMAN HEALTH

#### Reference values to be used in Risk Characterisation<sup>1</sup>

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term = OEL short term, 15					15000 ppm (1.5 %)
minutes reference					Ref: Directive
period					2006/15/EC
					European Directive in
					application
					of Directive
AELlong-term					98/24/EC 5000 ppm
= OEL, 8 hour time weighted					(0.5%)
average					Ref:
					Directive 2006/15/EC
					European
					Directive in
					application of Directive
					98/24/EC
ARfD					Not applicable,
					as exposure
					via
					food/feed is
					not expected

30

Assessment Report for carbon dioxide (PT15), finalised in the Biocidal Products Committee meeting on 17 June 2014:

Existing data on the subchronic toxicity of carbon dioxide are available, including data on man. However, it is acknowledged that these studies were carried out some time ago, and were therefore not carried out to current protocols or with current laboratory techniques. Given that these data are unavoidably weak, the current occupational exposure limit for safe working conditions with carbon dioxide has been used as the AEL value for the risk assessment. This is because the use of carbon dioxide as an avicide does not increase carbon dioxide concentrations above levels found naturally in the atmosphere, and these levels are well below established maximum occupational exposure limits for safe working conditions.

Occupational exposure studies have been carried out in humans exposed to an environment with high  $paCO_2$  values (the arterial carbon dioxide tension), such as brewery workers. Such data have been used previously by a number of regulatory authorities to set national, international and supranational maximum exposure limits for safe working conditions, and all of these exposure limits are in general agreement.

ADI			No relevant
			residues in
			food/feed
			expected

### Maximum residue limits or equivalent

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)

### **Specific reference value for groundwater**

Not required as no exposure is expected.

### Risk for industrial users

Not relevant.

### Risk for professional users

### **Systemic effects**

The biocidal product is identical to the active substance, and the proposed use (killing geese) is the reference use in the European dossier. In the Assessment Report for carbon dioxide (PT15), finalised in the Biocidal Products Committee meeting on 17 June 2014, the following is concluded regarding the risk for professional users:

Exposure of professional users to carbon dioxide during its use as avicide is considered to be negligible. Killing of large numbers of geese takes place 2 to 4 times per day during a maximum of 8 weeks per year. Emptying and/or re-entry of the container which is used for killing of geese takes place after the carbon dioxide has dropped to levels below occupational exposure limits in the safe working conditions (TWA 8 h: 5000 ppm = 0.5%). In rare cases when the professional user will need to enter the container room when the concentration of carbon dioxide is above 1.5%, PPE such as self-contained breathing apparatus (SCBA) should be used. The duration of the exposure during the incidental reentry of the container by professional users is not expected to exceed 15 minutes, therefore it is considered appropriate to compare the exposure levels with the short-term TWA 15 min of 1.5 %. For further personal protection a portable carbon dioxide detector, which gives an alerting signal when the carbon dioxide concentration exceeds safe levels (0.5%), is used when entering the container room shortly after use for killing of geese.

The safety limits for carbon dioxide (TWA 8 h of 0.5% [5000 ppm] and TWA 15 min of 1.5% [15000 ppm]) have resulted from a thorough evaluation of the properties of carbon dioxide by a number of regulatory authorities to set national, international and supranational maximum exposure limits for safe working conditions, and all of these exposure limits are in general agreement. Therefore no concern for adverse effects from exposure to carbon dioxide due to its application as an avicide exists for professional user

if exposure concentrations remain under the safety limits, and no further risk assessment has been performed for the professional use as an avicide.

#### **Combined scenarios**

No combined exposure is foreseen.

#### **Local effects**

Local effects are not expected from the proposed use of carbon dioxide.

#### Conclusion

It can be concluded that by using the following safety measures:

- 1: proper venting of the container used for killing of geese
- 2: monitoring of the CO2 concentration
- 3: re-entry of the container after the CO2 has dropped to levels below occupational exposure limits in the safe working conditions (TWA 8 h: 5000 ppm = 0.5%)
- 4: use of a self-contained breathing apparatus (SCBA) in case the limit value of 1.5% (TWA 15 min) is exceeded)

the exposure of professional users to carbon dioxide when it is as avicide is considered to be negligible. Within the framework of Regulation (EU) No 528/2012, the available information is deemed acceptable.

### Risk for non-professional users

As the gassing will only be performed by professionals, no exposure of non-professional users will occur.

### Risk for the general public

Bystanders/general public might be exposed to carbon dioxide when used as avicide. However, since application of carbon dioxide does not result in exposure of professional users above safe working limits, the exposure of bystanders/general public in a worst case situation is also considered not to exceed these safe limits.

#### Risk for consumers via residues in food

Application of carbon dioxide as avicide does not result in residues to which consumers might become exposed.

# Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant. The biocidal product is idential to the active substance that contains no substances of concern.

PT15

#### 2.3.6 Risk assessment for animal health

Exposure of non-target animals to carbon dioxide by the proposed use is not foreseen.

### 2.3.7 Risk assessment for the environment

For the product DUKE's Carbon Dioxide no new studies have been provided. DUKE's Carbon Dioxide is identical to the active substance carbon dioxide and is also the reference product in the CAR for carbon dioxide (PT15) and therefore no new data/information is required. The environmental risk assessment below is copied from the Assessment Report for carbon dioxide (PT15), finalised in the Biocidal Products Committee meeting on 17 June 2014.

### A. EFFECTS ASSESSMENT ON THE ENVIRONMENT

No ecotoxicological studies have been submitted since no additional risk for the environment is anticipated for the proposed use of carbon dioxide as an avicide.

Due to the particular nature of carbon dioxide, it has to be considered that carbon dioxide does not fulfil persistence criteria in any environmental criteria and has no bioaccumulation potential. Carbon dioxide has no PBT potential. In addition, carbon dioxide is not classified as hazardous to health according to EC Directive 67/548/EEC, nor are there any indications of toxicity such as endocrine disruption. The toxicity profile of carbon dioxide, coupled with the fact that it is unlikely to accumulate in the environment, means that there is a low risk of primary and secondary poisoning of birds and mammals. Geese killed with carbon dioxide are not disposed of in the environment, but processed for food and feed consumption or otherwise destroyed. Considering carbon dioxide's mode of action (suffocation), possible residues will not result in adverse effects in higher thropic levels including humans as the active substance is ingested orally.

### Further studies on fate and behaviour in the environment (ADS)

After being used as an avicide the carbon dioxide is released into the atmosphere where it mixes with the carbon dioxide already present. Carbon dioxide is a natural product of respiration in plants and animals and of combustion. The contribution from its use as an avicide to naturally occurring carbon dioxide concentrations will be negligible.

### **B. EXPOSURE ASSESSMENT**

The exposure assessment shows that:

There will be no exposure of the aquatic environment to carbon dioxide. Consequently, adverse effects to aquatic organisms and sediment dwelling organisms from the use of carbon dioxide in avicide products do not need to be considered.

Carbon dioxide will not enter sewage treatment plants and effects on micro-organisms in sewage treatment plants do therefore not need to be considered either.

Similarly for the terrestrial and atmospheric environmental compartments, there will be no increase in the levels of carbon dioxide in the atmosphere or soil outside normal atmospheric ranges from the use of carbon dioxide as an avicide.

The PEC was set to zero for all the compartments, meaning that the use of carbon dioxide as a biocide will not increase carbon dioxide concentrations outside natural ranges.

### C. RISK CHARACTERISATION

Given the effectively zero level of exposure expected in all environmental compartments from the use of carbon dioxide as an avicide, it has been concluded that there is no risk to the environment or wildlife.

### 2.3.8 Measures to protect man, animals and the environment

#### Man

- Carbon dioxide is intended for use by professional operators, and as such workers should be fully trained in its safe use.
- Avoid freezing of tubing material by controlled release of the gas from the cylinder and/or by simultaneous use of two or more cylinders. Carbon dioxide cylinders should be stored in a cool, dry ventilated place, out of reach of children and away from food, drink and animal feeding stuffs. Contact with large volumes of water should be avoided, as should extremes of temperature (e.g. below 0°C and 50°C).
- After the gassing, carbon dioxide is vented directly into the air where it is readily and rapidly dispersed and immediately diluted
- Ensure carbon dioxide concentration is less than 0.5% before entering the container used for killing geese. Measurement can be done by means of on-line monitoring equipment which is used during the killing of the geese or by means of personal monitoring equipment, intended to be used for occupational safety.
- Use a self-contained breathing apparatus (SCBA) in case the limit value of 1.5% (TWA 15 mins) is exceeded when the professional user will need to enter the container room.
- The airtightness of the container (slow or no filling of the container with CO2 in case the container is not airtight) is ensured by using continuous monitoring inside the container (a drop of CO2 would indicate a leak)

### Animal

No protective measures are required. Except for the target animals no exposure of animals is anticipated.

#### Environment

The instructions for use do not require measures in order to prevent emission to the environment.

### A. RECOMMENDED METHODS AND PRECAUTIONS

#### Storage:

Suck-back of water into the carbon dioxide cylinder must be prevented. Prevent backfeed of the product into the container. Use only properly specified equipment, which is suitable for this product, at its applied pressure and temperature. Contact your supplier if in doubt. Periodically check the system for leaks. Refer to the supplier's cylinder handling instructions.

### Handling and transport:

Secure cylinders to prevent them from falling. Keep container below 50°C in a well ventilated area. Ensure adequate ventilation. Wear protective gloves and safety shoes when handling cylinders. Make sure the driver is aware of the potential hazards of the load and knows what to do in case of an accident or an emergency. Before transporting product containers ensure that they are secure. Check that the cylinder valve is closed and not leaking. Make sure the cap nut (if present) is correctly fitted. Check the safety cap (if any) of the valve is properly attached. Provide adequate ventilation. Comply with applicable laws.

# B. IDENTITY OF RELEVANT COMBUSTION PRODUCTS IN CASES OF FIRE

Carbon dioxide does not generate combustion products in case of fire.

### C. SPECIFIC TREATMENT IN CASE OF AN ACCIDENT

### Personal precautions:

Evacuate area. Wear self-contained breathing apparatus when entering area unless atmosphere is proven to be safe. Ensure adequate ventilation.

# D. POSSIBILITY OF DESTRUCTION OR DECONTAMINATION FOLLOWING RELEASE

Not relevant.

# E. PROCEDURES FOR WASTE MANAGEMENT OF THE BIOCIDAL PRODUCT AND ITS PACKAGING

Empty gas cylinders are returned to the manufacturer.

# F. PROCEDURES FOR CLEANING APPLICATION EQUIPMENT WHERE RELEVANT

Not relevant.

# G. SPECIFY ANY REPELLENTS OR POISON CONTROL MEASURES INCLUDED IN THE PRODUCT

Not applicable.

### 2.3.9 Assessment of a combination of biocidal products

The biocidal product is not used in combination with other biocidal products.

### 2.3.10 Comparative assessment

Not relevant.

### 3 ANNEXES

### 3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

Since the biocidal product is identical to the active substance (for which the applicant is the notifier), and is also the reference product in the CAR for carbon dioxide (PT15), new studies have not been submitted.

### 3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

Not applicable.

### 3.3 NEW INFORMATION ON THE ACTIVE SUBSTANCE

New information on the active substance was not submitted.

### 3.4 RESIDUE BEHAVIOUR

Not applicable.

### 3.5 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX)

Since the biocidal product is identical to the active substance (for which the applicant is the notifier), and is also the reference product in the CAR for carbon dioxide (PT15), new efficacy studies have not been submitted. For the summary of the efficacy studies it is referred to the CAR.

### 3.6 CONFIDENTIAL ANNEX

No new confidential data have been submitted.