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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



Cullnox

Product type(s) 15

Active substance: Carbon dioxide

Case Number in R4BP: [BC-VR058335-08]

Evaluating Competent Authority: [BE]

Date: [04/10/2021]

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**Changes history table**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| NA-ADC | *BE* | BC-HB075558-41 | xx.xx.xxxx | Change of producer Active Substance | Chapter 2.1.1 |

#

# CONCLUSION

*Efficacy:*

The product Cullnox is used by professional pest control officers for killing captured nuisance geese (e.g. around airports). 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.

*Physico-chemical properties:*

This product is a pressurised gas composed of 100% CO2.

The product is a colourless and odourless gas (inert) under normal temperature and pressure conditions with a density of 1.977 kg/m³ at 1.013 bar and 0 oC and a relative density of 1.527 at 25 o.

Apart from the H statement for liquiefied gases “H280, contains gas under pressure; may explode if heated”, no classification and labelling is proposed for this product, given the lack of critical endpoints in terms of physico-chemical properties.

Being 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. The product is thus considered stable and the proposed shelflife is 5 years.

*Risk assessment for human health:*

This product is not classified.

No risk is anticipated for the professional user when all safety precautions have been taken (real time monitoring of carbon dioxide concentrations, breathing apparatus where necessary).

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)

5: Except for personnel no access is allowed in the working area

The exposure of professional users to carbon dioxide when it is as avicide is considered to

be negligible.

Regarding secondary exposure, bystanders (general public) is not supposed to be exposed to the biocidal product, knowing that this product is only intended to be used by professional users in the tight container dedicated to the pest control. 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.

In addition, for secondary exposure, the amount of carbon dioxide released into the atmosphere in negligible compared to the amounts present due to other sources

*Dietary risk assessment:*

No harmful residues are anticipated in food stuffs. It is further emphasized that product consists of food-grade carbon dioxide which is also used in beverages such as soft-drinks.

*Risk assessment for animal health:*

No risk is anticipated for animal health. During gassing of tight container, animals which do not need to be killed are translocated to a safe area. Therefore, exposure of non-target animals to carbon dioxide by the proposed use is not foreseen.

*Risk assessment for environment:*

This product is not classified.

The overall conclusion is that the use of product poses no risk for the environment.

Access to areas where the gassing is performed is only allowed for professionals and trained personnel. Where necessary they can be equipped with self-contained breathing apparatus and personal monitoring devices for carbon dioxide. During the gassing and venting on-line measurement of carbon dioxide concentrations in the treated area. No access to the container and surrounding areas is allowed to bystanders and animals not to be killed are removed before the gassing. No measures are taken to protect the environment since the product does not pose any risk to the environment.

*Endocrine disruption :*

Carbon Dioxide is not part of the list[[1]](#footnote-1) of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.

Therefore, BE eCA considers that there are no concerns regarding ED properties of Carbon Dioxide.

This product is composed of 100% CO2, therefore any SOC has been identified.

1. **ASSESSMENT REPORT**

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier** | **Country (if relevant)** |
| --- | --- |
|  | Carbon dioxide |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Total Culling Concept group BV |
| **Address** | Asterweg 16, 1031 HN Amsterdam |
| **Authorisation number** |  |
| **Date of the authorisation** |  |
| **Expiry date of the authorisation** |  |

#### Manufacturer(s) of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | Linde Gas Benelux |
| **Address of manufacturer** | Havenstraat 1, 3115 HC Schiedam |
| **Location of manufacturing sites** | Linde GasBotlekweg 1693179 KA Botlek RTThe Netherlands |

#### Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | Carbon dioxide |
| **Name of manufacturer** | Duke Faunabeheer |
| **Address of manufacturer** | Schoepenweg 24, 8243 PX, Lelystad |
| **Location of manufacturing sites** | Duke Faunabeheer Botlekweg 1693179 KA Botlek RTThe Netherlands |

### 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 [x]  PT15

No [ ]

#### 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** | Not listed in Annex VI of the CLP regulation |
| **Minimum purity / content** | 99.9 % v/v |
| **Structural formula** | O=C=O |

#### Candidate(s) for substitution

The active substance in the product does not meet the criteria set for candidates for substitution set in Article 10 of the BPR.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| **Carbon dioxide** | **Carbon dioxide** | **Active substance** | **124-38-9** | **204-696-9** | **Technical: 100% w/w** |
|  |  |  |  |  | **Pure : 99.9 % v/v****(food grade)** |

#### Information on technical equivalence

Assessment of technical equivalence of the active substance in Cullnox was not considered necessary. Cullnox is identical (same source) to the food grade carbon dioxide (purity ≥ 99.9 % v/v) which was assessed for listing of the substance on the Unionlist for PT15. In addition the level of impurities is lower than the generic and specific concentration limits which are set as trigger for classification according to REGULATION (EC) No 1272/2008.

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

The product does not contain substances of concern;

Remark : the active substance has EU OEL.



ED no info in the CAR.

#### Type of formulation

|  |
| --- |
| GA |

### Hazard and precautionary statements

**Classification and labelling of the products of the family according to the Regulation (EC) 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 statements | P410 + P403 - Protect from sunlight. Store in a well ventilated place. |
|  |
| Note | EIGA-As. Asphyxiant in high concentrations |

### Authorised use(s)

#### Use description

Table 2. Use # 1 –killing of captured wild geese – professional users

|  |  |
| --- | --- |
| **Product Type** | PT15 - Avicide |
| **Where relevant, an exact description of the authorised use** | Killing of captured wild geese |
| **Target organism (including development stage)** | Anser sp. – geese - adultsAnser sp. – geese - juvenilesBranta sp. – geese - adultsBranta sp. – geese - juveniles |
| **Field of use** | Control of nuisance geese |
| **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 minutesin an air tight container. The carbon dioxide concentration inthe container is monitored to ascertain that the requiredconcentration of 70-90% carbon dioxide is reached within 1minute and maintained for 5 minutes. |
| **Category(ies) of users** | trained professionals |
| **Pack sizes and packaging material** | 5 – 50 l gas cylindersCylinders which are used for food grade carbon dioxide areequipped with a dedicated valve (residual valve) to avoidcontamination of the contents of the cylinder. |

#### Use-specific instructions for use

|  |
| --- |
|  See general directions for use. |

#### Use-specific risk mitigation measures

|  |
| --- |
|  See general directions for use. |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| See general directions for use. |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| See general directions for use. |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| See general directions for use. |

### General directions for use

#### Instructions for use

|  |
| --- |
| *Manner and area of use:*Geese, captured during the period of moulting, are placed in an air tight container. Thecarbon dioxide gas is led from one or more gas cylinders into the container to aconcentration of 70-90% carbon dioxide. The gas concentration in the container is onlinemonitored by means of a carbon dioxide meter. The geese are kept in the containerfor at least 5 minutes.*Conditions of use:*To obtain sufficient efficacy, without unnecessary pain and suffering to the geese, thefollowing conditions for use are set:- the carbon dioxide flow into the container should be of such volume that the requiredconcentration 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 meterThe administration of the gas should be set at such a rate that the target concentration70 to 90 % (v/v) is reached in maximum 1 minute.This can be achieved by:1. a constant flow rate and adjustment of the size of the gassing chamber, for examplecompartmentalisation, based on the number of geese to be killed.2. a constant volume of the gassing chamber and adjustment of the flow rate based onthe 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 productPrecautions should be taken to avoid freezing of the tubing due to expansion of the gas. |

#### Risk mitigation measures

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| --- |
| Gas (Cullnox product or carbon dioxide) concentrations are measured inside the box. For re-entry, the in order to avoid exceeding of OELinhalation corresponding to 15000 ppm (for short term, 15 min/d) and 5000 ppm (for long term 8h/d), the technical and organisational measures shall be ensured (e.g. sensor, defined ventilation period). Use of a self-contained breathing apparatus (SCBA) in case the limit value of 1.5% (TWA 15 min) is exceeded.Proper venting of the container used for killing of geese 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.Except for personnel no access is allowed in the working area. Personnel working in this area is carrying personal gas monitors. Assure non target animals are not present in the structures/spaces/areas during fumigation. |

#### 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 highconcentrations. Possible symptoms are: loss of the moving ability or unconsciousness.The victim is not aware of the suffocation.Cullnox may displace oxygen. increase respiration and heart rate and cause rapid suffocation. Liquid Cullnox may cause frostbite. First-aid measures after inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. If not breathing, give artificial respiration, with supplemental oxygen given by qualified personnel. If breathing is difficult, qualified personnel should give oxygen. Call a physician. First-aid measures after skin contact: For exposure to liquid or cold vapour, immediately warm frostbite area with warm water not to exceed 41°C. Water temperature should be tolerable to normal skin. Maintain skin warming for at least 15 minutes or until normal colouring and sensation have returned to the affected area. In case of massive exposure, remove clothing while showering with warm water. Seek medical evaluation and treatment as soon as possible. First-aid measures after eye contact: Immediately flush eyes thoroughly with water for at least 15 minutes. Hold the eyelids open and away from the eyeballs to ensure that all surfaces are flushed thoroughly. Contact an ophthalmologist immediately. |

#### Instructions for safe disposal of the product and its packaging

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| After use the treated area is vented into the atmosphere under controlled conditions. The packaging is returned to the product supplier and refilled. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

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

### Other information

|  |
| --- |
| Application codes |

### 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 | 5 – 50 L | Steel | Dedicated valve (residual valve) to avoid contamination of the contents of the cylinder | Professional | Yes |

### Documentation

#### Data submitted in relation to product application

No new information on the active substance within the framework of authorisation of the product Cullnox is provided.

#### Access to documentation

Access to all data submitted for approval of carbon dioxide for use as active substance for PT15 biocides were was granted by Duke Faunabeheer, Lelystad, The Netherlands.

## Assessment of the biocidal product

### Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – avicide

|  |  |
| --- | --- |
| Product Type(s) | 15 |
| Where relevant, an exact description of the authorised use | / |
| Target organism (including development stage) | Birds. All developmental stages |
| Field of use | Indoor, gassing of animal stables. |
| Application method(s) | Gassing |
| Application rate(s) and frequency | Single application when necessary |
| Category(ies) of user(s) | Professional users |
| Pack sizes and packaging material | 5 – 50 L, Steel gas cylinders  |

### Physical, chemical and technical properties

The applicant has provided a letter of access to the data of the CAR of the active substance as well as for the data of the reference product DUKE’s carbon dioxide.

The biocidal product is identical to the active substance, ≥ 99.9% (v/v) carbon dioxide. Considering this, and the LoA provided by the applicant, the physico-chemical and technical properties of the products are identical to those described in the CAR of the active substance.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (v/v)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state, colour and odour at 20 °C and 101.3 kPa | Waived | ≥ 99.9 | Odourless, colourless gas | NL-PIB-0016, NL-PIB-0019 (SDS)Topham, 2000 |
| Acidity / alkalinity | Waived  | Not applicable for the formulation type |
| Density (gas) at 1.013 bar  | Not known | ≥ 99.9 | 1.977 kg/m³ at 0°CRelative density (air = 1): 1.527 at 25°C (from CAR) | NL-PIB-0016, NL-PIB-0019 (SDS); Topham, 2012 |
| Storage stability test – **accelerated storage** | Waived  | 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. Moreover, from the CAR of the a.s. it is known that thermodynamically,carbon dioxide is stable under atmospheric pressure up to approximately 300°C. Over thistemperature, it dissociates into carbon monoxide and oxygen. At normal temperature, carbon dioxide is stable from 10-5 to 100 atm.Based on these considerations, the applicant proposes a shelf life of 5 years, as in the reference product of the CAR. BE eCA agrees with the explanation on stability and requests no test. 5 years stability are accepted. | EN-ISO 9809-1, 2010; EN-ISO 9809-3, 2010 |
| Storage stability test – **long term storage at ambient temperature** |
| Storage stability test – **low temperature stability test for liquids** | Waived | Not applicable for the formulation type |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Waived | The product is packed in steel gas cylinders, impermeable for light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Waived | The product is packed in steel gas cylinders and does not meet water; therefore, the effect of humidity is not of application. Carbon dioxide is formed as end-product during the combustion of organic material. Therefore, the product is considered to be stable at ambient temperature conditions. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Waived  | Carbon dioxide is supplied in containers designed and manufactured in accordance with proven industry standards for carbon dioxide: - EN-ISO 9809-1:2010 (Gas cylinders –  Refillable seamless steel gas cylinders - Design, construction and testing - Part 1: Quenched and tempered steel cylinders with tensile strength less than 1100 MPa) - EN-ISO 9809-3:2010 (Gas cylinders - Refillable seamless steel gas cylinders - Design, construction and testing - Part 3: Normalized steel cylinders). Containers manufactured to this specification will ensure that there is no reactivity between the carbon dioxide and its container.Because of this, experimental determination of the storage stability of carbon dioxide will not provide any useful additional information for the risk assessment. |
| Wettability | Waived | Not applicable for the formulation type |
| Suspensibility, spontaneity and dispersion stability | Waived | Not applicable for the formulation type |
| Wet sieve analysis and dry sieve test | Waived | Not applicable for the formulation type |
| Emulsifiability, re-emulsifiability and emulsion stability | Waived | Not applicable for the formulation type |
| Disintegration time | Waived | Not applicable for the formulation type |
| Particle size distribution, content of dust/fines, attrition, friability | Waived | Not applicable for the formulation type |
| Persistent foaming | Waived | Not applicable for the formulation type |
| Flowability/Pourability/Dustability | Waived | Not applicable for the formulation type |
| Burning rate — smoke generators | Waived | Not applicable for the formulation type |
| Burning completeness — smoke generators | Waived | Not applicable for the formulation type |
| Composition of smoke — smoke generators | Waived | Not applicable for the formulation type |
| Spraying pattern — aerosols | Waived | Not applicable for the formulation type |
| Physical and chemical compatibility | Waived | Not applicable, the product is an inert gas which is not intended to be used in combination with other products |
| Degree of dissolution and dilution stability | Waived | Not applicable for the formulation type |
| Surface tension | Waived | Not applicable for the formulation type |
| Viscosity | Waived | Not applicable for the formulation type |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| This product is a colourless and odourless gas under normal temperature and pressure conditions with a density of 1.977 kg/m³ at 1.013 bar and 0 oC and a relative density of 1.527 at 25 o. Being 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. The product is thus considered stable and the proposed shelflife is 5 years. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | Waived  | Carbon dioxide is not an explosive since there are no chemical groups associated with explosive properties present in the molecule. |
| Flammable gases | Waived | Carbon dioxide is not flammable (often used as extinguishing agent for fires involving flammable liquids) |
| Flammable aerosols | Waived  | Not applicable for the formulation type  |
| Oxidising gases | Waived | Carbon dioxide is formed as end product of the combustion of organic material or reaction of oxygen with organic material, and thus can not contribute to the combustion of other material more than air does. |
| Gases under pressure | - | ≥ 99,9 vol % | Liquefied gasH280: contains gas under pressure, may explode if heated | NL-PIB-0019 (SDS) |
| Flammable liquids | Waived  | Not applicable for the formulation type  |
| Flammable solids | Waived  | Not applicable for the formulation type  |
| Self-reactive substances and mixtures | Waived  | Not applicable for the formulation type  |
| Pyrophoric liquids | Waived  | Not applicable for the formulation type  |
| Pyrophoric solids | Waived  | Not applicable for the formulation type  |
| Self-heating substances and mixtures | Waived  | Not applicable for the formulation type  |
| Substances and mixtures which in contact with water emit flammable gases | Waived  | Not applicable for the formulation type Moreover, carbon dioxides dissolves readily in water in a well known reaction emitting no flammable gas. |
| Oxidising liquids | Waived  | Not applicable for the formulation type  |
| Oxidising solids | Waived  | Not applicable for the formulation type  |
| Organic peroxides | Waived | Carbon dioxide does not contain the bivalent –O-O- structure. |
| Corrosive to metals | Waived | The product is a gas and, according to the Guidance on the Appicaton of the CLP Criteria, neither the corrosivity of gases nor the formation of corrosive gases is currently covered by CLP classes and therefore not applicable.  |
| Auto-ignition temperatures of products (liquids and gases) | Waived | Carbon dioxide is a stable end-product of a combustion of organic material, and thus does not ignites spontaneously in air |
| Relative self-ignition temperature for solids | Waived  | Not applicable for the formulation type  |
| Dust explosion hazard | Waived  | Not applicable for the formulation type  |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is an inert gas under normal temperature and pressure conditions. Apart from the H statement for liquiefied gases “H280, contains gas under pressure; may explode if heated”, no classification and labelling is proposed for this product, given the lack of critical endpoints in terms of physico-chemical properties.  |

### Methods for detection and identification

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. The list of possible impurities to be analysed covers a broad range of solid, liquid and gaseous chemicals. 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 (EIGA 2008). For more details, please see the CAR of the active substance.

Hand held portable devices for monitoring of carbon dioxide in air under ambient conditions for occupational safety are commercially available. A calibrated device can measure in a range from 0 to 9999 ppm CO2 measuring range, with an accuracy of one digit and a resolution of 1 ppm CO2 (p.e. Testo 535).

No methods for **measurement of carbon dioxide in formulations** are submitted since there is no formulation process involved for the anticipated use of carbon dioxide in the context of this application.

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 biocide 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 biocide 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 and is part of the metabolism. Carbon dioxide used to kill these organisms cannot be distinguished from this.

• 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).

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| In conclusion, no methods are required to determine carbon dioxide in formulations or carbon dioxide residues in soil, air, water, body fluids, food or other relevant products following its use as a biocide. |

### Efficacy against target organisms

####

#### Function and field of use

MG03 – PEST CONTROL : PT15 - AVICIDE

Cullnox is used by professional pest control officers for killing

captured nuisance geese (e.g. around airports) by gassing with CO2 ( CAS 124-38-9) in an airtight container.

Fields of use:

1. nuisance geese that endanger public safety and health at and around airports;

2. invasive alien birds;

3. geese causing eutrophication

#### 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, for example, at and around airports. Objects to be protected are airplanes taking off or landing. The aim is to reduce the chance of collision between geese and airplanes.

The main goal of the product is to:

1. kill nuisance geese that endanger public safety and health at and around airports;

2. kill nuisance geese that soil public and domestic buildings;

3. kill invasive alien geese;

4. kill geese as a measure to control populations in case biodiversity is endangered by their increased numbers and/or aggressive behaviour;

5. kill geese as a measure to control populations in case due to their increased numbers the health of the environment is endangered (eutrofication);

#### 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.

#### 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.

#### Efficacy data

Cullnox 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, Cullnox is sufficientlyactive as an avicide against geese. |

#### 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

#### Known limitations

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

#### 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:

o the gas concentration in the container should be (on-line) monitored by means of a carbon dioxide meter

o 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.

#### Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product is not intended to use the product in combination with other biocides

### Risk assessment for human health

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

|  |
| --- |
| **Data waiving** |
| Information requirement | 8.1.1 Skin irritation / corrosion |
| Justification | It is technically not possible to perform irritation studies to eye or skin and to perform a skin corrosion/irritation 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 requirement | 8.1.2 Eye irritation |
| Justification | It is technically not possible to perform irritation studies to eye or skinand to perform an eye irritation study because carbon dioxide is agas. 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 requirement | Respiratory tract irritation |
| Justification | The principle route of exposure to carbon dioxide will be inhalation,which should however be viewed in relation to the concentration ofcarbon dioxide in exhaled air of approximately 5%. National,international and supranational maximum exposure limits for safeworking conditions for carbon dioxide are TWA 8 hrs of 0.5% (5000ppm) and TWA 15 mins of 1.5% (15000 ppm). These levels are belowthe concentration in expired air. Therefore, it is considered notnecessary to require a respiratory tract irritation study. |

***Skin sensitization***

|  |
| --- |
| **Data waiving** |
| Information requirement | 8.3.1 Skin sensitization |
| 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 | 8.3.2 Respiratory sensitization |
| Justification | Studies of the response of the body to increased carbon dioxideconcentrations were performed. There was no evidence of respiratorysensitisation by carbon dioxide. Therefore, it is considered notnecessary to require this study. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |
| --- |
| **Data waiving** |
| Information requirement | 8.5.1 Acute toxicity: oral |
| 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 activesubstance) in human volunteers exposed to increased carbon dioxideconcentrations in air, reveal that the body adapts to 2% carbondioxide, that it tolerates 9% for at least 12 minutes, and that 10.6%carbon dioxide was experienced as very unpleasant. An OccupationalExposure Limit (OEL) of 5,000 ppm (0.5% - 8-h time weightedaverage) was established in Directive 2006/15/EC in implementationof Directive 98/24/EC. Therefore, it is considered not necessary torequire this study. |

| **Summary table of animal studies on acute inhalation toxicity** |
| --- |
| **Method,Guideline,****GLP status , Reliability** | **Species,Strain,Sex,No/group** | **Test substance, form** **Concentration, Type of administration**  | **Signs of toxicity**  | **LC50** | **Reference** |
| No guideline followed, non-GLP, rel. 2 | Fischer 344 rats, male, 6 per conc. level | Gas, 7 concentration levels, head only exposure, 30 minutes | Death during or within 2 minutes after termination of exposure | 470,000 ppm95% confidence limits 430,000and 510,000 ppm. | Levin et al., 1989 |
| Cn x t relationship | Rat (Wistar, adult, male and female) | Head only inhalation / 40, 43 and 50% CO2 / 40%: 180 and 240 min; 43%: 15, 20, 30, 60 and 90 min; 50%: 10, 15 and 20 min. | decreased breathing frequency during exposure; increased tidal volume; shallow breathing; piloerection; hunched posture; ataxia; lethargy; increased breathing rate after exposure; In some or all decedents petechiae, red or dark red patches on the lungs, discolouration of the lungs, an incompletely collapsed lung and a trachea and a larynx containing foam, discharge from the nose or mouth and a red discolouration of the thymus.  | 40 – 43% range: LC50 estimates between 40 and 47% independent of exposure time.Shortest exposure time 15 minutes.44 – 50% range: No reliable estimate | Muijser et al., 2014 |

| **Summary table of human data on acute inhalation toxicity** |
| --- |
| **Type of data/ report, Reliability** | **Test substance** | **Relevant information about the study** | **Observations** | **Reference**  |
|  | Carbon dioxide  | 12 males7-14% CO2 in inhaled air / 10-20 minutes | Cardio-respiratory and central nervous system effects at all dose levels. Loss of consciousness at 10.6% CO2. | Sechzer et al. (1960) |
|  | Carbon dioxide | Man/-/-/52.6-9.3% CO2 in inhaled air / 12-15 minutes | Slight cardiovascular effects below 5.3% CO2. Sharp increase of effects above this level. 9% CO2 was tolerated for at least 12 minutes. | Blackburn et al. (1972) |
|  | Carbon dioxide | Man/-/male/41 6.7% highest conc. tested / 6 minutes | Cardiovascular response increased above 5.16% CO2. 6.7% CO2 was tolerated for at least 6 min. | Cullen and Eger (1974) |

|  |
| --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | 0.5% CO2 |
| Justification for the selected value | Excessive levels of CO2 were used in animal studies compared to the studies in human volunteers. For this reason the latter are considered more relevant. Effects of increased CO2 levels in human occur immediately and were observed in man at levels to approximately 5% in the inhaled air. Under normal situations the CO2 level in exhaled air is 4.15 ± 0.82% (Dodig et al, 2008). These values are well above the indicative limit value for CO2 of 0.5% CO2 for occupational exposure during an 8 hour work period (91/322/EEC, 2006/15/EC). 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 a biocide exists for the professional user if exposure concentrations remain under the safety limits, and no further risk assessment has been performed for the professional use as a biocide. |
| Classification of the product according to CLP and DSD | Not classified |

*Acute toxicity by dermal route*

|  |
| --- |
| **Data waiving** |
| Information requirement | 8.5.1 Acute toxicity: dermal |
| Justification | It is not technically feasible 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 requirement | 8.6 Dermal absorption |
| Justification | It is not technically possible to determine the dermal absorption ofcarbon dioxide. Furthermore, as carbon dioxide is a gas, dermalexposure will not be a significant route of exposure. Any carbon dioxide which is absorbed via the skin will be added to the pool of carbon dioxide which is well regulated to maintain a stable state in the body. 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 is identical to the active substance.

***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 food or feed to carbon dioxide as a result of the use of the biocidal

product will not lead to increased concentrations in food or feed products.

#### 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** |
| --- |
| **Exposure path** | **Primary (direct) exposure**  | **Secondary (indirect) exposure**  |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **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** | **Primary exposure. Description of scenario** | **Exposed group** |
| 1. | Use of the biocidal product | Primary exposure:Prior to the use of product 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 theatmosphere. 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 |
| 2. |  | Primary exposure:Bystanders is not supposed to be exposed to the biocidal product, knowing that this product is only intended to be used by professional users in the tight container dedicated to the pest control.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. | general public (bystanders) |
| 3. |  | 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***

No industrial use of Cullnox as biocide is anticipated.

***Professional exposure***

The killing of animals takes place in an air-tight container, which is filled with product from a gas cylinder. The concentration of product in the treated area is monitored with a carbon dioxide meter with a read-out unit placed on the outside the structure. No exposure of professional users is expected to occur during the filling of the container and during the actual process of gassing.

Product is applied in closed spaces according to standard operating procedures. During the treatment the presence of unprotected personnel and general public in these spaces is prohibited. After use the container is vented and re-entry of the container is allowed after the carbon dioxide has dropped below occupational exposure limits in the safe working conditions (TWA 8h: 5000 ppm = 0.5%). To ensure safe working conditions the carbon dioxide concentration is monitored by stand alone and/or personal monitoring equipment. In case the room needs to be entered for short term activities and the limit value of 1.5% (TWA 15 min) is exceeded the use of a self-contained breathing apparatus (SCBA) has to be taken into account.

Following use of product the container (area) is vented is released in the atmosphere where it mixes with the carbon dioxide already present. Gassing of container (area) is performed according a working procedure.

Gas (product and oxygen) concentrations are measured inside and outside the container. Except for personnel no access is allowed in the working area. Personnel working in this area is carrying personal gas monitors. A specific area upwind is assigned for other personnel and bystanders. Here an area gas monitor is placed which alarms (acoustic and light signal) when it measures a product concentration >3%.

In case of windlessness industrial fans will be placed to force the gas in the wright direction.

***Scenario [1]***

No exposure scenarios are worked out since safe working levels for carbon dioxide have been established and real time monitoring of workplace concentration takes place. Professionals are only exposed to carbon dioxide levels below these safe working levels.

**Calculations for Scenario [1]**

No calculations were performed.

**Further information and considerations on scenario [1]**

No local effects are expected during normal use and correct functioning of the gassing system. However during malfunctioning resulting in leakage of the liquefied gas dermal exposure which can result in frostbite can occur.

*Combined scenarios*

No calculations were performed. It is further emphasized that the concentration of carbon dioxide in exhaled air is approximately 5%, which is 10-fold the 8-hour time weighted average occupational exposure limit.

***Non-professional exposure***

***Scenario [2]***

Bystanders is not supposed to be exposed to the biocidal product, knowing that this product is only intended to be used by professional users in the tight container dedicated to the pest control.

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.

**Calculations for Scenario [2]**

No calculations were performed.

**Further information and considerations on scenario [n]**

No relevant information and considerations not covered above is available

*Combined scenarios*

/

***Exposure of the general public***

***Scenario [3]***

No exposure scenarios are worked out. 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 biocide is considered negligible.

**Calculations for Scenario [3]**

No calculations were performed.

**Further information and considerations on scenario [n]**

No relevant information and considerations not covered above are available.

*Combined scenarios*

No calculations were performed.

***Monitoring data***

Man is continuously exposed to carbon dioxide present in the atmosphere, exhaled air, consumption of carbonated drinks etc… Hence monitoring of possible exposure to carbon dioxide from Euthesate is considered not relevant

***Dietary exposure***

Animals which were killed with carbon dioxide might be used for human consumption or might be processed for use in animal feed production. 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 animals killed with carbon dioxide is considered negligible. Application of carbon dioxide as biocide does not result in residues to which consumers might become exposed. The carbon dioxide which is used as biocide is food grade and does not contain impurities which can form a concern with respect to indirect exposure by food.

Residue definitions

*List of scenarios*

No scenarios for dietary exposure are given

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

Non-biocidal use of carbon dioxide comprises many areas. Plants use carbon dioxide for photosynthesis. Carbon dioxide is involved in the production of refrigeration systems, welding systems, water treatment processes, production of organic and inorganic chemicals, enhancement of oil recovery, firefighting and is used as propellant of aerosols.

| **Summary table of main representative dietary exposure scenarios** |
| --- |
| **Scenario number** | **Sector of use** | **Intended use** | **Reference value(s)** |
| 4. | Food industry | Carbonated drinks.  | - |
| 5.  | Plantprotection | Use as rodenticide and insecticide. | No MRL required (included inAnnex IV of COMMISSIONREGULATION (EC) 149/2008) |

No additional risk assessment is performed for exposure to carbon dioxide following the consumption of carbonated drinks since this is out of the scope of the BPR. Furthermore carbon dioxide levels are well regulated in the body.

*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 a biocide can be excluded.

**Scenario [n]**

No exposure scenarios are worked out.

**Calculations for estimating livestock exposure for Scenario [n]**

No calculations were performed.

**Further information and considerations on scenario [n]**

No relevant information and considerations not covered above are available.

Conclusion

There is no significant exposure of livestock to carbon dioxide following the use of Cullnox as biocide.

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

**Scenario 6**

Animals 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 animals killed with carbon dioxide is considered negligible.

**Conclusion**

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

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

The product is for professional use only

**Conclusion**

Not applicable

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

Not relevant.

***Summary of exposure assessment***

Professional users

No calculation performed. See explanations below.

Indirect (secondary) exposure

Primary exposure:

Not relevant.

Secondary exposure:

No calculation performed. See explanations below.

#### Risk characterisation for human health

**Reference values to be used in Risk Characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AELshort-term |  |  |  |  | 15000 ppm |
| = OEL short | (1.5 %) |
| term, 15 |  |
| minutes | Ref: |
| reference | Directive |
| period | 2006/15/EC |
|  | European |
|  | Directive in |
|  | application |
|  | of Directive |
|  | 98/24/EC |
| AELlong-term |  |  |  |  | 5000 ppm |
| = OEL, 8 hour | (0.5%) |
| time weighted |  |
| 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 |

1 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 paCO2 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.

The primary mode of action of toxicity from carbon dioxide is "respiratory acidosis". Carbon dioxide levels build up in the blood causing drowsiness, leading to stupor, coma and ultimately death. Death occurs very quickly if carbon dioxide levels in the blood do not drop. Critical end points and assessment factors are not further addressed. A number of regulatory authorities has set national, international and supranational maximum exposure limits for safe working conditions, and all of these exposure limits are in general agreement (TWA8h: 5000 ppm = 0.5% and short-term exposure limit TWA15min: 15000 ppm = 1.5%). These limit values are further used in the risk assessment.

**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)

Birds such as geese which were killed with CO2 might be used for human consumption or might be processed for use in animal feed production. However, as CO2 is a gas, during processing free exchange of the carbon dioxide with the surrounding atmosphere occurs. The exposure to significant levels of CO2 following consumption of birds killed with CO2 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 is food grade and does not contain impurities which can form a concern with respect to indirect exposure by food. No maximum residue limit needs to be derived.

**Specific reference value for groundwater**

After being used as a biocide the carbon dioxide is released into the atmosphere where it

mixes with the carbon dioxide already present. The contribution from its use as an

biocide to naturally occurring carbon dioxide concentrations will be negligible. Carbon dioxide is a natural product of respiration in plants and animals and of combustion. The concentration of carbon dioxide in water is in equilibrium with the carbon dioxide in the atmosphere. Since the contribution of the amount of carbon dioxide which is released into the atmosphere following gassing of rooms is negligible no reference value for groundwater has been calculated.

***Risk for industrial users***

No industrial use of the product is foreseen. Therefore, risk for industrial users is not relevant.

***Risk for professional users***

**Systemic effects**

The killing of animals takes place in an air-tight container, which is filled with product from a gas cylinder. The concentration of product in the treated area is monitored with a carbon dioxide meter with a read-out unit placed on the outside the structure. No exposure of professional users is expected to occur during the filling of the container and during the actual process of gassing.

Product is applied in closed spaces according to standard operating procedures. During the treatment the presence of unprotected personnel and general public in these spaces is prohibited. After use the container is vented and re-entry of the container is allowed after the carbon dioxide has dropped below occupational exposure limits in the safe working conditions (TWA 8h: 5000 ppm = 0.5%). To ensure safe working conditions the carbon dioxide concentration is monitored by stand alone and/or personal monitoring equipment. In case the room needs to be entered for short term activities and the limit value of 1.5% (TWA 15 min) is exceeded the use of a self-contained breathing apparatus (SCBA) has to be taken into account.

Following use of product the container (area) is vented is released in the atmosphere where it mixes with the carbon dioxide already present. Gassing of container (area) is performed according a working procedure.

Gas (product and oxygen) concentrations are measured inside and outside the container. Except for personnel no access is allowed in the working area. Personnel working in this area is carrying personal gas monitors. A specific area upwind is assigned for other personnel and bystanders. Here an area gas monitor is placed which alarms (acoustic and light signal) when it measures a product concentration >3%.

In case of windlessness industrial fans will be placed to force the gas in the wright direction.

**Local effects**

During malfunctioning resulting in leakage of the liquefied gas dermal exposure which can result in frostbite can occur.

**Conclusion**

No risk is anticipated for the professional user when all safety precautions have been taken (real time monitoring of carbon dioxide concentrations, breathing apparatus where necessary).

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 15 min: 15000ppm = 1.5% and 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

5: Except for personnel no access is allowed in the working area

6: 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 exposure of professional users to carbon dioxide when it is as avicide is considered to

be negligible.

***Risk for non-professional users***

No non-professional use of the product is foreseen. Therefore, risk for non-professional users is not relevant.

***Risk for the general public***

**Systemic effects**

Bystanders is not supposed to be exposed to the biocidal product, knowing that this product is only intended to be used by professional users in the tight container dedicated to the pest control. 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.

In addition, for secondary exposure, the amount of carbon dioxide released into the atmosphere in negligible compared to the amounts present due to other sources

**Local effects**

None.

**Conclusion**

No risk is anticipated for the general public.

***Risk for consumers via residues in food***

No harmful residues are anticipated in food stuffs. It is further emphasized that product consists of food-grade carbon dioxide which is also used in beverages such as soft-drinks.

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

Not applicable

### Risk assessment for animal health

No risk is anticipated for animal health. During gassing of tight container, animals which do not need to be killed are translocated to a safe area. Therefore, exposure of non-target animals to carbon dioxide by the proposed use is not foreseen.

### Risk assessment for the environment

For the product no new studies have been provided. This product is identical to the active substance carbon dioxide which is also the reference product in the CAR for carbon dioxide (PT15) and therefore no new data/information is required.

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 amounts will be negligible. Carbon dioxide is an end product of biodegradation of organic substances. Testing for the biodegradability of carbon dioxide and testing for route and rate of degradation in soil or water is therefore not applicable.

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. 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 biocide 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. After being released into the atmosphere the carbon dioxide will participate in the equilibrium between air, water and soil by passive diffusion. An therefore pose no risk for life of non target-organisms in these compartments. It is concluded that there is no unacceptable risk for non-target organisms from the use of carbon dioxide as a avicide.

#### Effects assessment on the environment

No ecotoxicological studies have been submitted since no risk for the environment is anticipated for the proposed use of carbon dioxide as a 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 regulation REGULATION (EC) No 1272/2008, 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 no risk of primary and secondary poisoning.

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

This product is identical to the active substance carbon dioxide and the reference product in the CAR for carbon dioxide (PT15). Carbon dioxide is not classified for ecotoxicity, hence the product is also not classified for ecotoxicity.

***Further Ecotoxicological studies***

No further ecotoxicological studies were performed. Following use product is released in the atmosphere where it mixes with the carbon dioxide already present.

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

This product is applied in tight container. Before application non-target organisms are removed from these spaces, hence these organisms are not at risk when product is used as avicide.

***Supervised trials to assess risks to non-target organisms under field conditions***

No data available. Non-target organisms are not exposed when using product as avicide.

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

Non-target organisms are not exposed when using product as avicide. Furthermore this product is food grade carbon dioxide which amongst others is used in alcoholic and non-alcoholic beverages.

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

No secondary ecological effects are anticipated. This product is applied in a tight container. Following use product is diluted in the atmosphere where it mixes with the carbon dioxide already present.

***Foreseeable routes of entry into the environment on the basis of the use envisaged***

Following use product is released in the atmosphere where it mixes with the carbon dioxide already present.

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

Following use product is released in 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. Carbon dioxide is used by plants during their growth.

***Leaching behaviour (ADS)***

Not applicable, this product is a gas.

***Testing for distribution and dissipation in soil (ADS)***

Not applicable, following use product is released in the atmosphere where it mixes with the carbon dioxide already present. Carbon dioxide in the atmosphere is in equilibrium with the carbon dioxide in water, sediment and soil where there is free exchange with the atmosphere.

**Distribution**

See rationale above.

**Dissipation**

See rationale above.

***Testing for distribution and dissipation in water and sediment (ADS)***

Not applicable, following use product is released in the atmosphere where it mixes with the carbon dioxide already present. Carbon dioxide in the atmosphere is in equilibrium with the carbon dioxide in water, sediment and soil where there is free exchange with the atmosphere.

**Distribution**

See rationale above.

**Dissipation**

See rationale above.

***Testing for distribution and dissipation in air (ADS)***

The total amount of carbon dioxide released globally into the atmosphere in 2017 was between 35 and 55.1 gigatonnes (Olivier and Peters, 2018). The global mean concentration of carbon dioxide is approximately 400 ppm (National Oceanic and Atmospheric Administration, 2019). Annual amounts of carbon dioxide released into the atmosphere from the use of product are estimated to be 300 tonnes which is considered negligible. When used product is released in the atmosphere where it is allowed freely to mix with the carbon dioxide already present.

**Distribution**

See rationale above.

**Dissipation**

See rationale above.

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

Not relevant. This product is a gas which is used indoors and released in the atmosphere after use. The product is not sprayed near surface waters.

**Acute aquatic toxicity**

Not applicable, following use product is released in the atmosphere where it mixes with the carbon dioxide already present. Carbon dioxide in the atmosphere is in equilibrium with the carbon dioxide in water where there is free exchange with the atmosphere.

**Estimated aquatic bioconcentration**

Not applicable, following use product is released in the atmosphere where it mixes with the carbon dioxide already present. Carbon dioxide which is dissolved in water is used by plants as substrate for photosynthesis. Carbon dioxide is one of the end products of metabolism in animals, its concentration is well regulated in the body and excess is secreted in the water.

***If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)***

Not applicable. This product is a gas and is used indoors.

#### Exposure assessment

No exposure assessment has been performed. This product consists of >99% carbon dioxide. After use the carbon dioxide is released into the atmosphere where it freely mixes with the carbon dioxide there present and subsequently participates in the free exchange of carbon dioxide between air, water and soil.

***Emission estimation***

**Scenario [1]**

The total amount of carbon dioxide released globally into the atmosphere in 2017 was between 35 and 55.1 gigatonnes (Olivier and Peters, 2018). The global mean concentration of carbon dioxide is approximately 400 ppm (National Oceanic and Atmospheric Administration, 2019). Annual amounts of carbon dioxide released into the atmosphere from the use of product are estimated to be 300 tonnes per year which is considered negligible.

Since this product solely consists of carbon dioxide which is released in the atmosphere, the amount released is negligible to the amount already present originating from natural and anthropogenic sources and the concentration is in equilibrium between the individual environmental compartments no calculations for these compartments were performed.

***Fate and distribution in exposed environmental compartments***

This product solely consists of carbon dioxide which is released in the atmosphere. Carbon dioxide is the substrate for photosynthesis in living organisms. In this process carbon dioxide is converted into sugars by reaction with water under the influence of sunlight. The sugars subsequently can be used for several metabolic processes in the organism.

Since the product solely consists of carbon dioxide which is released in the atmosphere, the amount released is negligible to the amount already present originating from natural and anthropogenic sources and the concentration is in equilibrium between the individual environmental compartments no calculations for these compartments were performed.

***Primary and secondary poisoning***

Primary poisoning

Since the product solely consists of carbon dioxide which is released in the atmosphere, the amount released is negligible to the amount already present originating from natural and anthropogenic sources, the concentration is in equilibrium between the individual environmental compartments, the concentration in living organisms is well controlled, the substance does not accumulate or is a substrate for photosynthesis where the substance is transferred to carbohydrates, primary poisoning is not addressed.

Secondary poisoning

Since the product solely consists of carbon dioxide which is released in the atmosphere, the amount released is negligible to the amount already present originating from natural and anthropogenic sources, the concentration is in equilibrium between the individual environmental compartments, the concentration in living organisms is well controlled, the substance does not accumulate or is a substrate for photosynthesis where the substance is transferred to carbohydrates, secondary poisoning is not addressed.

#### Risk characterisation

***Atmosphere***

Risk for the atmosphere is not applicable from the use of product. The total annual amount of carbon dioxide released globally into the atmosphere in 2017 was between 35 and 55.1 gigatonnes (Olivier and Peters, 2018). The global mean concentration of carbon dioxide is approximately 400 ppm (National Oceanic and Atmospheric Administration, 2019). Annual amounts of carbon dioxide released into the atmosphere from the use of product are estimated to be 300 tonnes per year which is considered negligible.

***Sewage treatment plant (STP)***

Risk for the STP is not applicable from the use of product. Since the product solely consists of carbon dioxide which is released in the atmosphere, the amount released is negligible to the amount already present originating from natural and anthropogenic sources and the concentration is in equilibrium between the individual environmental compartments.

***Aquatic compartment***

Risk for the aquatic compartment is not applicable from the use of product. Since the product solely consists of carbon dioxide which is released in the atmosphere, the amount released is negligible to the amount already present originating from natural and anthropogenic sources and the concentration is in equilibrium between the individual environmental compartments. In plants carbon dioxide is an essential substrate for photosynthesis.

***Terrestrial compartment***

Risk for the terrestrial compartment is not applicable from the use of product. Since the product solely consists of carbon dioxide which is released in the atmosphere, the amount released is negligible to the amount already present originating from natural and anthropogenic sources and the concentration is in equilibrium between the individual environmental compartments. In plants carbon dioxide is an essential substrate for photosynthesis.

***Groundwater***

Risk for groundwater is not applicable from the use of product. Since the product solely consists of carbon dioxide which is released in the atmosphere, the amount released is negligible to the amount already present originating from natural and anthropogenic sources and the concentration is in equilibrium between the individual environmental compartments.

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning is not applicable. Carbon dioxide is a substrate for the synthesis of carbohydrates by photosynthesis or the end product of metabolism of organic substances. In both case levels of carbon dioxide in the living organism are well related by physiological processes.

Secondary poisoning

Secondary poisoning is not applicable. Carbon dioxide is a substrate for the synthesis of carbohydrates by photosynthesis or the end product of metabolism of organic substances. In both case levels of carbon dioxide in the living organism are well related by physiological processes.

***Mixture toxicity***

Mixture toxicity is not relevant. Cullnox consists of food grade carbon dioxide and does not contain substances of concern.

***Aggregated exposure (combined for relevant emission sources)***

No aggregated exposure assessment is required. The total annual amount of carbon dioxide released globally into the atmosphere in 2017 was between 35 and 55.1 gigatonnes (Olivier and Peters, 2018). The global mean concentration of carbon dioxide is approximately 400 ppm (National Oceanic and Atmospheric Administration, 2019). Annual amounts of carbon dioxide released into the atmosphere from the use of product are estimated to be 300 tonnes per year which is considered negligible.

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| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The overall conclusion is that the use of product poses no risk for the environment. |

### Assessment of ED properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Cullnox:

1. Assessment of the ED properties of the active substances in product:
* According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As Carbon Dioxide is not part of the list[[2]](#footnote-2) of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.
* Therefore, BE eCA considers that there are no concerns regarding ED properties of Carbon Dioxide.
1. Assessment of the ED properties of non-active substances (co-formulants) in Cullnox:
* The product does not contain substance of concern regarding the ED prorpieties.

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

Access to areas where the gassing is performed is only allowed for professionals and trained personnel. Where necessary they can be equipped with self-contained breathing apparatus and personal monitoring devices for carbon dioxide. During the gassing and venting on-line measurement of carbon dioxide concentrations in the treated area. No access to the container and surrounding areas is allowed to bystanders and animals not to be killed are removed before the gassing. No measures are taken to protect the environment since the product does not pose any risk to the environment.

### Assessment of a combination of biocidal products

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

### Comparative assessment

A comparative assessment is not required. The product consists of food grade carbon dioxide and does not contain substances of concern.

#### Screening phase

See rationale above (2.2.11).

#### Tier IA

See rationale above (2.2.11).

#### Tier IB

See rationale above (2.2.11).

#### Tier II

See rationale above (2.2.11).

#### Overall conclusion

A comparative assessment is not required. The product consists of food grade carbon dioxide and does not contain substances of concern.

# Annexes

## List of studies for the biocidal product

| Author(s)  | Year  | Title  | Bibliographic source  | GLP Study (Yes/No)  | Published (Yes/No)  | Data Protection Claimed (Yes/No)  | Data Owner  | IUCLID Section No  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Anonymous |  | Kooldioxide Foodgrade | NL-PIB-0016 | No | Yes | No | Linde Gas Benelux B.V. |  |
| Anonymous |  | Kooldioxide Foodgrade | NL-PIB-0019 | No | Yes | No | Linde Gas Benelux B.V. | 4.5 |
| Blackburn JP et al.  | 1972 | Paco2 and the Pre-ejection Period:The Paco2/lnotropy Response Curve | Anesthesiology 37 (3), 268-276 1972 | No | Yes | No | – |  |
| Blackshaw JK et al. | 1988 | The behaviour of chickens, mice and rats during euthanasia with chloroform, carbon dioxide and ether. | Laboratory Animals 22, 67-75 | No | Yes | No | – | 6.1, 6.7 |
| Cullen and Eger  | 1974 | Cardiovasculdr Effects of CarbonDioxide in Man | Anesthesiology 41 (4), 345-349 | No | Yes | No | – |  |
| EN-ISO 9809-1 | 2010 | Gas cylinders - Refillable seamless steel gas cylinders - Design, construction and testing -Part 1: Quenched and tempered steel cylinders with tensile strength less than 1 100 MPa  |  | No | Yes | No | – |  |
| EN-ISO 9809-3 | 2010 | Gas cylinders — Refillable seamless steel gas cylinders — Design, construction and testing —Part 3:Normalized steel cylinders |  | No | Yes | No | – |  |
| Gerritzen MA et al. | 2004 | On-Farm Euthanasia of Broiler Chickens: Effects of Different GasMixtures On Behavior and Brain Activity | Poultry Science 83:1294–1301 | No | Yes | No | – | 6.1, 6.7 |
| Gerritzen MA et al. | 2013 | Multistage carbon dioxide gas stunning of broilers | Poultry Science 92: 41–50 | No | Yes | No | – | 6.1, 6.7 |
| Levin et BC et al. | 1989 | Synergistic effects of nitrogen dioxide and carbon dioxide following acute inhalation exposures in rats | National Institute of Standards and TechnologyNISTIR 89-4105 | No | Yes | No | – | 8.5.2 |
| Muijser H et al. | 2014 | Acute toxicity of high concentrations of carbon dioxide in rats | Regulatory Toxicology and Pharmacology 69, 201–206 | No | Yes | No | – | 8.5.2 |
| National Oceanic and Atmospheric Administration | 2019 | Trends in Atmospheric Carbon Dioxide | https://www.esrl.noaa.gov/gmd/ccgg/trends/global.html | No | Yes | No | – |  |
| Olivier and Peters | 2018 | Trends in global CO2 and total greenhouse gas emissions | PBL Netherlands Environmental Assessment AgencyThe Hague, 2018PBL publication number: 3125 | No | Yes | No | – |  |
| Poole and Fletcher | 1995 | A Comparison of Argon, Carbon Dioxide, and Nitrogen in a Broiler Killing System | Poultry Science 74:1218-1223 | No | Yes | No | – | 6.1, 6.7 |
| Sechzer PH et al.  | 1960 | Effect of C02 inhalation on arterial pressure,ECG and plasma catecholamines andI 7-0H corticosteroids in normal man1 | J. Appl. Ph ysiol. 15(3): 454-458. | No | Yes | No | – |  |
| Topham S | 2000 | Carbon Dioxide | Ullman's encyclopedia of industrial chemistry | No | Yes | No | – | 3.3,  |
| Wageningen Livestock Research | 2010 | Killing of wild geese with CO2 and argon |  | No | Yes | No | – | 6.1, 6.7 |

## Output tables from exposure assessment tools

No exposure assessment tools were used for the assessment of the product.

## New information on the active substance

No relevant new information on the active substance within the framework of authorisation of the product is provided

## Residue behaviour

Residue behaviour is not relevant. Levels of carbon dioxide are well controlled in living organisms and excess is freely exchanged with the atmosphere.

## Summaries of the efficacy studies (B.5.10.1-xx)

See iuclid file

## Confidential annex

The composition of the product is provide in the confidential annex

## Other

No other information is submitted for approval of the product.

1. Please refer to CA-September18.Doc.7.5.a-final . [↑](#footnote-ref-1)
2. Please refer to CA-September18.Doc.7.5.a-final . [↑](#footnote-ref-2)