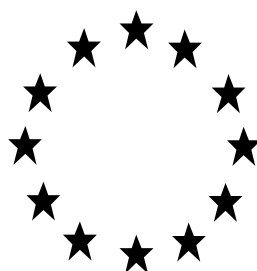


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A
BIOCIDAL PRODUCT FOR SIMPLIFIED
AUTHORISATION APPLICATION**

(submitted by the competent authority)



BG CO2

Product type 19

Carbon dioxide as included in the Annex I of Regulation (EU)
No 582/2012

Case Number in R4BP: BC-YH074113-35

Competent Authority: FR CA

Date: 01/02/2023

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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
SA-APP	FR CA	BC-YH074113-35	01/02/2023	<i>Initial assessment</i>	

1 Conclusion

BG CO2 is a gaz biocidal product containing carbon dioxide as active substance. The product is used as a repellent (product type 19) by professionals and non-professionals for the control of mosquitoes outdoor.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the use against mosquitoes by professional and non-professional users, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended use of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

Following evaluation, the biocidal product does meet the conditions required for simplified authorisation as defined in Article 25 of Regulation (EU) No 528/2012, i.e.:

1. The active substances Carbon dioxide is listed in Annex I of Regulation (EU) 528/2012 and satisfies the restriction that it is only for use in ready-for-use gas canisters functioning together with a trapping device. with restrictions applied;
2. The biocidal product does not contain any substance of concern;
3. The biocidal product does not contain any nanomaterials;
4. The biocidal product is sufficiently effective;
5. The handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

A classification according to Regulation (EC) No 1272/2008¹ is necessary. Detailed information on classification and labelling is provided in section 2.8 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

The biocidal product does not contain any substances of concern. .

The biocidal product should be considered not to have endocrine-disrupting properties.

The biocidal product does not contain any active substances having endocrine-disrupting properties.

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Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturers of the biocidal product is listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance in the biocidal product are met. The manufacturer of the active substance is listed in section 1.5 of the SPC.

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Conclusions of the assessments for each area

The intended use as applied for by the applicant has been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards were identified. Contains gas under pressure; may explode if heated – H280. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Carbon dioxide is listed in Annex I of regulation (EU) No 528/2012 under Category 6 and an analytical method has been provided during the assessment of the active substance.

As the product BG CO₂ is composed of 100% of carbon dioxide and as the carbon dioxide is provided in cylinders fully filled with carbon dioxide, no additional analytical method is necessary.

Analytical methods for monitoring active substance residues in soil, air, water, human body fluids and tissues are not required for simplified procedures according to Article 20(1)(b) of the BPR.

Efficacy against target organisms

Based on the efficacy data presented, it can be concluded that the product BG CO₂ in combination with a suction trap is efficient to attract mosquitoes (*Culex* spp, *Aedes* spp, *Anopheles* spp and *Coquillettidia* spp) outdoor at the application rate of 0.5 kg/24h (an equivalent to 175 mL/min).

Risk assessment for human health

No substance of concern regarding Human Health was identified.

The handling of the product and its intended use do not require any personal protective equipment.

Risk assessment for the environment

No substance of concern regarding environment was identified.

2 Information on the biocidal product

2.1 Product type(s) and type(s) of formulation

Identifier	Country (if relevant)
	BG CO2 BG-sentinel 2 BG-Pro BG-Protector BG-Booster CO2 BG-Booster

2.1.1.1 Manufacturer(s) of the products

Name of manufacturer	Biogents SA
Address of manufacturer	Weißenburgstr. 22 93055 Regensburg Germany
Location of manufacturing sites	- Kremser Straße, 9 93055 Regensburg Germany - Rentokil Initial Supplies, Webber Road, Knowsley Industrial Park L33 7SR Liverpool United Kingdom

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

Active substance	Carbon dioxide
Name of manufacturer	Rentokil Initial Supplies
Address of manufacturer	Webber Road, Knowsley Industrial Park L33 7SR Liverpool United Kingdom
Location of manufacturing sites	Webber Road, Knowsley Industrial Park L33 7SR Liverpool United Kingdom

Table 2.1 Product type(s) and type(s) of formulation

Product type(s)	PT19
Type(s) of formulation	GA – Gas

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use number ¹	Use description ²	PT ³	Target organisms ⁴	Application method ⁵	Application rate ⁶ (min-max)	User category ⁷	Conclusion (eCA/refMS) ⁸	Comment (eCA/refMS) ⁹
1	Outdoor mosquito attraction	19	Mosquitoes (<i>Culex spp</i> , <i>Aedes spp</i> , <i>Anopheles spp</i> and <i>Coquillettidia spp</i>).	Bait application in combination with a suction trap. A trap containing CO ₂ bottle of 2 to 37,5kg (175 mL/min) for a use 24H/24H	A trap containing CO ₂ bottle (175 mL/min) for a use 24H/24H	Professional and non-professional	Acceptable	

¹ Use number (as applied for), as indicated in the SPC

² Title of the specific use (as applied for), as indicated in the SPC

³ Product type(s) of the use(s)

⁴ Target organisms, group of organisms

⁵ Application method for the specific use

⁶ Min-max. application rate of the product for the specific use

⁷ User category(ies), e.g. general public, non-professional, professional, industrial

⁸ eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

⁹ If the use is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and indicate the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

2.3 Identity and composition

The determination whether the identity and composition of the biocidal product are identical or not identical to the identity and composition of the product(s) evaluated in connection with the inclusion of the active substance(s) in Annex I of Regulation (EU) No 528/2012, is not applicable.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

Main constituent(s)	
Common name	Carbon Dioxide
Chemical name	Carbon Dioxide
EC number	204-696-9
CAS number	124-38-9
Index number in Annex VI of CLP	-
Minimum purity / content	100%
Structural formula	O=C=O

2.5 Information on the source(s) of the active substance(s)

The information on the source(s) of the active substance(s) is not applicable.

2.6 Candidate(s) for substitution

Not relevant, the active substance is not candidate for substitution or exclusion.

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

	Classification	Labelling
Hazard Class and Category code	<i>Press. Gas (Comp)</i>	
Hazard Pictograms		
Signal word(s)	<i>[Warning]</i>	<i>[Warning]</i>
Hazard statements	H280: Contains gas under pressure; may explode if heated	H280: Contains gas under pressure; may explode if heated
Precautionary statements*		P403: Store in a well-ventilated place. P410: Protect from sunlight The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements		
Notes		

*P-statements that are excluded based on the risk assessment or the intended use of the product², are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

² Section 3 of the CA note of Q&A concerning the content of some SPC sections. Document is available at <https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b>.

2.9 Letter of access

No Letter of Access to the active substance and/or to the product have been submitted.

2.10 Data submitted in relation to product authorisation

No new data on the active substance(s) and substance(s) of concern have been submitted.

2.11 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging ¹	Size/volume of the packaging ²	Material of the packaging ³	Type and material of closure(s)	Intended user ⁴	Compatibility of the product with the proposed packaging materials (Yes/No)
Gas Cylinder	2- 37.5 kg	Steel	Dedicated valve (residual valve) to avoid contamination of the contents of the cylinder	Professional and non-professional	Yes

¹ Type of packaging e.g. bottle, rolls, can, barrel, tank.

² Size for primary packaging (closed packaging that preserves the biocidal product, prevents leakage during storage and is removed or opened before use) and detailed volume in the case of individual packaging intended to be used to prevent human exposure and facilitate the use of the product.

For rolls or individual products such as wipes, the dimension of product / amount of individual products should be reported here: Height*Length*Width for rolls / number and weight of wipes.

³ For metallic packaging, it should be indicated if there is a varnish layer; in the same way, the nature of plastic packaging should be reported. For sprayer sold with packaging, the nature of the material should be added.

⁴ Intended user, e.g. professional, non-professional

3.2 Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa			Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. Moreover, the biocidal product is the same as the active substance.	
3.1.1.	Physical state at 20 °C and 101.3 kPa	-	-	Gas at 20°C, 101.3 kPa	CAR, IIIB 3.1
3.1.2.	Colour at 20 °C and 101.3 kPa	-	-	Gas is colourless at 20°C, 101.3 kPa	CAR, IIIB 3.1
3.1.3.	Odour at 20 °C and 101.3 kPa	-	-	Gas is odourless at 20°C, 101.3 kPa	CAR, IIIB 3.1
3.2.	Acidity, alkalinity and pH value	Not applicable as CO ₂ is a gas	CAR, IIIB 3.5	Not applicable as CO ₂ is a gas	CAR, IIIB 3.5
3.3.	Relative density / bulk density	Relative density: 1.527	CAR, IIIA 3.1.3	Relative density: 1.527	CAR, IIIA 3.1.3
3.4.1.1.	Storage stability test – accelerated storage	Statement		BG CO ₂ contains 100% carbon dioxide in a gas cylinder. Carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage. There is no reactivity between active substance and containers.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.1.2.	Storage stability test – long-term storage at ambient temperature	statement		The product has a shelf-life of at least 2 years. No degradation of carbon dioxide takes place under ambient temperature and pressure. Carbon dioxide is thermodynamically stable and not expected to degrade. It is stored in gas tight packaging. The product is in this case the active substance and therefore the storage stability has already been addressed during the evaluation of the active substance.	<div data-bbox="1845 571 2036 635" style="background-color: black; width: 65px; height: 40px; margin-bottom: 5px;"></div> No report number <div data-bbox="1845 719 2036 783" style="background-color: black; width: 65px; height: 40px; margin-bottom: 5px;"></div> No report number
3.4.1.3.	Storage stability test – low temperature stability test for liquids	-	-	BG CO2 contains 100% carbon dioxide in a gas cylinder. Carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage.	-
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – light	Statement	-	The product contains 100% of carbon dioxide compressed in an opaque metal cylinder (steel). No effects of light is expected.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product - temperature and humidity	Statement	-	Effect of Humidity and temperature has not been assessed . The product contains 100% of carbon dioxide compressed in a metal canister. There are no effects on content of the active substance and technical characteristics of the biocidal product.	
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	Statement	-	The product contains 100% of carbon dioxide compressed in a cylinder (metal: steel). Carbon dioxide is a chemically inert substance and does not react with steel.	
3.5.1.	Wettability [<i>indicate the concentration tested</i>]	-	-	Not relevant as the product is a gas.	-
3.5.2.	Suspensibility, spontaneity, and dispersion stability	-	-	Not relevant as the product is a gas.	-
3.5.3.	Wet sieve analysis and dry sieve test	-	-	Not relevant as the product is a gas.	-
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not relevant as the product is a gas.	-
3.5.5.	Disintegration time	-	-	Not relevant as the product is a gas.	-
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	-	-	Not relevant as the product is a gas.	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.7.	Persistent foaming	-	-	Not relevant as the product is a gas.	-
3.5.8.	Flowability/pourability/dustability	-	-	Not relevant as the product is a gas.	-
3.5.9.	Burning rate – smoke generators	Statement	-	Not relevant as product is a ready-to-use compressed gas closed into a dedicated valve (no combustion)	
3.5.10.	Burning completeness – smoke generators	Statement	-	Not relevant as product is a ready-to-use compressed gas closed into a dedicated valve (no combustion)	
3.5.11.	Composition of smoke – smoke generators	Statement	-	Not relevant as product is a ready-to-use compressed gas closed into a dedicated valve (no combustion)	
3.5.12.	Spraying pattern – aerosols / spray	Statement	-	Not relevant as product is a ready-to-use compressed gas closed into a dedicated valve (no combustion)	
3.6.1.	Physical compatibility	Statement	-	BG CO2 contains 100% carbon dioxide in a gas cylinder. BG CO2 is a ready-to-use product so it is not added to any other chemicals during its normal use. It is for these reasons that it is not necessary to submit data on the physical and chemical compatibility of BG CO2 with other products, chemicals or	
3.6.2.	Chemical compatibility				

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				active ingredients.	
3.7.	Degree of dissolution and dilution stability	-	-	Not relevant as the product is a gas.	-
3.8.	Surface tension	-	-	Not relevant as the product is a gas.	-
3.9.	Viscosity	-	-	Not relevant as the product is a gas.	-

Table 3.3 Conclusion on physical, chemical, and technical properties**Conclusion on physical, chemical, and technical properties**

The appearance of the product is a colourless and odourless gas. BG CO2 contains 100% carbon dioxide in gas cylinder. Carbon dioxide is a thermodynamically and chemically stable compound which is not expected to degrade on storage. No stability study is provided to demonstrate the stability of product. FR CA proposes a shelf life of 2 years (standard value).

Its technical characteristics are acceptable for a gas formulation.

Implications for labelling: None

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w))	Results	Reference
4.1.	Explosives	Statement	-	BG CO2 contains 100% carbon dioxide in a gas canister. Carbon dioxide is thermodynamically stable and therefore does not exhibit explosive properties.	Doc A3 PT14 BPD Assessment Report 2007
4.2.	Flammable gases	Statement	-	Carbon dioxide is a non-flammable gas that does not support combustion.	Doc A3 PT14 BPD Assessment Report 2007
4.3.	Flammable aerosols	Statement	-	Not relevant as the product BG CO2 contains 100% of carbon dioxide compressed in a canister, which is not known to be a flammable substance. Furthermore, the product is not an aerosol.	
4.4.	Oxidising gases	Statement	-	Examination of the structural formula of carbon dioxide,	- Doc A3 PT14 BPD Assessment

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w))	Results	Reference
				along with the fact that it is widely accepted that carbon dioxide is thermodynamically stable, suggests that carbon dioxide will not exhibit oxidising properties. Moreover, the substance contains oxygen and are chemically bonded to carbon- Carbon dioxide has no oxidizing properties.	Report 2007
4.5.	Gases under pressure	Statement	-	The product is a ready-to-use compressed gas, which is classified as H280.	
4.6.	Flammable liquids	Statement	-	Not relevant as the product is a gas.	
4.7.	Flammable solids	Statement	-	Not relevant as the product is a gas.	
4.8.	Self-reactive substances and mixtures	Statement	-	Not relevant as the product is a gas.	
4.9.	Pyrophoric liquids	Statement	-	Not relevant as the product is a gas.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w))	Results	Reference
4.10.	Pyrophoric solids	Statement	-	Not relevant as the product is a gas.	
4.11.	Self-heating substances and mixtures	Statement	-	The substance is not known to be a self-heating substance.	
4.12.	Substances and mixtures which in contact with water emit flammable gases	Statement	-	The substance is soluble in water. The substance may react with water to generate carbonic acid, which is not a flammable gas. No emission of flammable gases is expected in water contact.	
4.13.	Oxidising liquids	Statement	-	Not relevant as the product is a gas.	
4.14.	Oxidising solids	Statement	-	Not relevant as the product is a gas.	
4.15.	Organic peroxides	Statement	-	Not relevant as the product is a gas.	
4.16.	Corrosive to metals	Statement	-	Carbon dioxide is not known to be corrosive metal. Not relevant as the product is a gas.	
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Statement	-	Carbon dioxide is a non-flammable gas that does not support	Doc A3 PT14 BPD Assessment Report

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w))	Results	Reference
				combustion.	2007
4.17.2.	Relative self-ignition temperature for solids	Statement	-	Not relevant as the product is a gas.	
4.17.3.	Dust explosion hazard	Statement	-	Not relevant as the product is a gas.	

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
<p>The active substance and the product are identical, physical, chemical and technical properties of the active substance is also applicable for the product BG CO2.</p> <p>The product is not flammable, does not present any self-ignition temperature, and has no explosive or oxidising properties.</p> <p><u>Implication concerning labelling:</u> Contains gas under pressure; may explode if heated – H280</p>

3.4 Methods for detection and identification

Carbon dioxide is listed in Annex I of regulation (EU) No 528/2012 under Category 6 and an analytical method has been provided during the assessment of the active substance.

As the product BG CO2 is composed of 100% of carbon dioxide and as the carbon dioxide is provided in bottles and canisters fully filled with carbon dioxide, no analytical methods has been provided.

Table 3.6 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
As the product BG CO2 is composed of 100% of carbon dioxide and as the carbon dioxide is provided in bottles and canisters fully filled with carbon dioxide, no analytical method is necessary.
Analytical methods for monitoring active substance residues in soil, air, water, human body fluids and tissues are not required for simplified procedures according to Article 20(1)(b) of the BPR.

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

The product BG CO₂ is a ready-to-use CO₂-based product intended to be used to attract mosquitoes outdoor, in combination with a suction trap.

The organisms to be protected are humans and animals.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

The product BG CO₂ acts by attracting the target organisms.


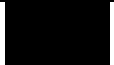
Mosquitoes are attracted by the attractive effect of carbon dioxide substance. Once in the proximity of the releasing device, mosquitoes are trapped by aspiration.


For mosquitoes and other biting and nuisance insects which are attracted by 'raised levels' of carbon dioxide, the mode of action is not entirely known. However, nerve receptors in the insect are triggered by raised levels of carbon dioxide, compared to normal background levels, and fly in the direction of the raised level gradient. The reason for flying in the direction of the raised carbon dioxide gradient is that 'raised levels' of carbon dioxide are associated with the presence of animals, especially mammals, and quite commonly humans, which are the food source for the blood-sucking mosquitoes.

According to Cooperband (2006a): "Female mosquitoes detect changes in carbon dioxide concentration as minute as 50 ppm, via sensilla on their maxillary palps (Grant & O'Connell, 1996). When a host-seeking female encounters a plume of carbon dioxide, she orients upwind using optomotor anemotaxis (Kennedy, 1939; Daykin et al., 1965). The structure of the plumes of carbon dioxide and other host-odour kairomones plays an important role in the attraction of *Aedes aegypti* (L.) mosquitoes. In a Y-tube olfactometer, orientation behaviour of *Ae. aegypti* varied with plume structure and odour, with a filamentous presentation of carbon dioxide inducing improved upwind movement over a homogenous cloud of carbon dioxide (Geier et al., 1999).

3.5.3 Efficacy data

Table 3.7 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
PT19 Attractant	CO ₂ released from a gas cylinder using BG-booster CO ₂ set The set is a pressure regulator to which is fixed a plastic tube. This tube can be attached directly to the suction trap	<i>Culex</i> spp, <i>Coquillettidia</i> spp, <i>Anopheles</i> spp, <i>Aedes</i> spp and <i>Culiseta</i> spp	Field Test, 3 sites outdoor During the experiments in three field sites, one suction trap was run with the addition of carbon dioxide from a standard CO ₂ gas cylinder. The CO ₂ is released from the gas cylinder through the BG-booster CO ₂ set (consisting of an adjustable pressure regulator to which is fixed a plastic tube, attached directly to the trap or to an emitter nozzle fixed to the trap - see picture below).  The release rates of CO ₂ were controlled daily, using an electronic flowmeter for CO ₂ The same set was run without the addition of CO ₂ as control trap. One trap was run with the addition of carbon dioxide using the BG-booster CO ₂ set at the recommended 0.5 kg / 24 h	The traps that released carbon dioxide using the BG-Booster CO ₂ set captured substantially higher numbers of female mosquitoes. In all three tests, a total of 4459 female mosquitoes were captured using carbon dioxide, compared to 659 females without CO ₂ . Catch mosquitoes rates fulfil the efficacy criteria of the ECHA efficacy guidance (2021) vol II parts B/C, i.e a ratio of 4:1 of the insects trapped in the trap with attractant compared to the control trap within the test period		6.7.001 Key study

		<p>(an equivalent of 175 ml/min), the other one was run without the addition of CO₂.</p> <p>Traps were continuously kept running. After 24 hours, the catch bags of each trap were collected and frozen to kill and preserve the catch, and the locations of the traps were exchanged.</p> <p>Two models of suction traps were used in the experiments:</p> <ul style="list-style-type: none">- BG-Pro (see picture left bellow): used in sites 2 and 3, in its standing, BG-Sentinel-type (right) configuration- BG-Sentinel 2 (right): used in site 1  <p>The traps used in the study did not use other lure than CO₂.</p>			
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Test site 1: "Wagenburg", Regensburg, Germany:

The trap used: BG-Sentinel 2.

Experiments were performed continuously for six days between the 31st May and the 12th June, 2017.

Temperature: Mean maximum daily 25.1°C (max. 33.5°C, min 18.5°C); Mean minimum daily 12.8°C (max. 17.5°C, min. 7.5°C)

RH: 62% (max. 94%, min 30%)

Release CO₂ rate: 0.5 kg/24h (equivalent to 175 ml/min)

Trap running with CO₂ and control trap (without CO₂) were placed at a different location, separated by 20 m.

Test site 1: "Wagenburg", Regensburg, Germany:

Mosquitoes (all females) attracted with CO₂: 205 mosquitoes from nine species.

Total Mosquitoes (females) attracted without CO₂: 2

Genera attracted: *Culex* spp, *Culiseta* spp*, *Aedes* spp and *Anopheles* spp.

Table2: total catches for BG-Sentinel 2 mosquito trap in site 1 "Wagenburg" for six days 24-h-periods

	<i>Culex pipiens</i>	<i>Aedes</i> spp	<i>Anopheles</i> spp
Trap with CO ₂	89	106	3
Trap control (without CO ₂)	2	0	0

*For *Culiseta* spp: 1 caught with CO₂ and 0 without CO₂

<p><u>Test site 2: "Kremser Street", Regensburg, Germany:</u></p> <p>The trap used: BG-Pro in its standing, BG-Sentinel-type configuration.</p> <p>Experiments were performed continuously for twelve days between July 9th and July 23rd, 2020.</p> <p>Temperature: Mean maximum daily 30.4°C (max. 38.0°C, min. 21.8°C); Mean minimum daily 21.0°C (max. 27.1°C, min. 13.6°C)</p> <p>RH: 64% (max. 93%, min 47%)</p> <p>Release CO₂ rate: 0.5 kg/24h (equivalent to 175 ml/min)</p> <p>Trap running with CO₂ and control trap (without CO₂) were placed at a different location, separated by 15 m.</p>	<p><u>Test site 2: "Kremser Street", Regensburg, Germany:</u></p> <p>Mosquitoes attracted with CO₂: 1281 from seven species (1261 were females)</p> <p>Mosquitoes attracted without CO₂: 499 (421 were females)</p> <p>Genera attracted: <i>Culex spp</i>, <i>Coquillettidia spp</i>, <i>Aedes spp</i> and <i>Anopheles spp</i>.</p> <p>Table2: total catches for BG-pro mosquito trap in site 2 "Kremser Street" for twelve 24-h-periods</p> <table border="1" data-bbox="1265 566 1879 853"> <thead> <tr> <th></th> <th>Culex pipiens</th> <th>Aedes spp</th> <th>Coquillettidia spp</th> <th>Anopheles spp</th> </tr> </thead> <tbody> <tr> <td>Trap with CO₂</td> <td>475</td> <td>692</td> <td>79</td> <td>7</td> </tr> <tr> <td>Trap control (without CO₂)</td> <td>359</td> <td>50</td> <td>9</td> <td>1</td> </tr> </tbody> </table>		Culex pipiens	Aedes spp	Coquillettidia spp	Anopheles spp	Trap with CO ₂	475	692	79	7	Trap control (without CO ₂)	359	50	9	1
	Culex pipiens	Aedes spp	Coquillettidia spp	Anopheles spp												
Trap with CO ₂	475	692	79	7												
Trap control (without CO ₂)	359	50	9	1												

		<p><u>Test site 3: "Irl", Regensburg, Germany</u></p> <p>The trap used: BG-Pro in its standing, i.e. the BG-Sentinel-type configuration.</p> <p>Experiments were performed continuously for 28 days between August 2nd and September 14th, 2021.</p> <p>Temperature: Mean maximum daily 24.0°C (max. 33.2°C, min. 15.6°C); Mean minimum daily 17.0°C (max. 23.7°C, min. 12.7°C)</p> <p>RH: 77% (max. 94%, min. 70%).</p> <p>Release CO₂ rate: 0.5 kg/24h (equivalent to 175 ml/min)</p> <p>Trap running with CO₂ and control trap (without CO₂) were placed at a different location, separated by 20 m.</p>	<p><u>Test site 3: "Irl", Regensburg, Germany</u></p> <p>Mosquitoes attracted with CO₂: 3014 from seven species (2993 were females)</p> <p>Mosquitoes attracted without CO₂: 328 (236 were females)</p> <p>Gerera attracted: <i>Culex</i> spp, <i>Coquillettidia</i> spp, <i>Culiseta</i> spp, <i>Aedes</i> spp and <i>Anopheles</i> spp.</p> <p>Table3: total catches for BG-Pro mosquito trap in site 3 "Irl" for 28 24h periods</p> <table border="1" data-bbox="1263 539 1883 826"> <thead> <tr> <th></th> <th>Culex pipiens</th> <th>Aedes spp</th> <th>Coquillettidia spp</th> <th>Anopheles spp</th> </tr> </thead> <tbody> <tr> <td>Trap with CO₂</td> <td>488</td> <td>1766</td> <td>556</td> <td>135</td> </tr> <tr> <td>Trap control (without CO₂)</td> <td>163</td> <td>28</td> <td>54</td> <td>24</td> </tr> </tbody> </table>		Culex pipiens	Aedes spp	Coquillettidia spp	Anopheles spp	Trap with CO ₂	488	1766	556	135	Trap control (without CO ₂)	163	28	54	24		
	Culex pipiens	Aedes spp	Coquillettidia spp	Anopheles spp																
Trap with CO ₂	488	1766	556	135																
Trap control (without CO ₂)	163	28	54	24																

3.5.4 Efficacy assessment

Three field studies have been conducted to demonstrate the attractiveness of the product BG CO₂. The suction traps (BG-Pro and BG-Sentinel) were baited with carbon dioxide which is released thanks to BG-Booster CO₂ (pressure regulator) from the product BG CO₂. The release rate of 0.5 kg/24h (an equivalent to 175 ml/min) were tested in the three sites. Baited traps have been compared to unbaited traps, the same set without CO₂ (control traps).

In the three sites, the set traps baited with CO₂ showed significant catch mosquito rates in comparison with the set traps without CO₂.

The large majority of mosquitoes captured were females.

At the site 1 "Wagenburg", catches rates were lower than the other sites because the test was conducted in early June when mosquito populations are still building up. The site is also lacking the proximity to productive mosquito breeding sites.

The test sites with the highest catch numbers were site 2 "Kremser Street" and site 3 "Irl", which are especially productive mosquito environments and where the tests were performed later in the summer (July and August/September, respectively), at times when mosquito populations have built up.

In site 2 "Kremser Street", control trap (without CO₂) catches a high rate of mosquitoes. This effect is observed in places with high mosquito densities. Nonetheless, the traps releasing carbon dioxide at 0.5 kg / 24 h (an equivalent of 175 mL/min), significantly improved the catch rates. The results of the field efficacy tests demonstrate that the product BG CO₂ in combination with a suction trap, at the rate of 0.5 kg/24h (an equivalent to 175 mL/min), attracts mosquitoes (*Culex* spp, *Aedes* spp, *Anopheles* spp and *Coquillettidia* spp) outdoor and fulfils globally the efficacy criteria of the ECHA efficacy guidance (2021) vol II parts B/C, i.e a ratio of 4:1 of the insects trapped in the trap with attractant compared to the control trap within the test period.

3.5.5 Conclusion on efficacy

Based on the efficacy data presented, it can be concluded that the product BG CO₂ in combination with a suction trap is efficient to attract mosquitoes (*Culex* spp, *Aedes* spp, *Anopheles* spp and *Coquillettidia* spp) outdoor at the application rate of 0.5 kg/24h (an equivalent to 175 mL/min).

3.5.6 Occurrence of resistance and resistance management

Up to now, no resistance has been identified in the literature review in any flying insect species, which is attracted by carbon dioxide.

However, the authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).

3.5.7 Known limitations

None.

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

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

3.6 Risk assessment for human health

3.6.1 Assessment of effects on human health

There are no human health data available for the product. The assessment, and classification and labelling are based on the agreed endpoints for the active substance. The classification of the product BG CO2 has been set according to the calculation rules laid down in the CLP Regulation 1272/2008/EC.

The product BG CO2 does not contain any classified ingredient and therefore is not classified for human health.

3.6.2 Available toxicological data relating to substance(s) of concern

No substances of concern regarding human health were identified.

3.6.3 Available toxicological data relating to endocrine disruption

Not relevant as no non-active substances were identified.

3.6.4 Exposure assessment and risk characterisation for human health

The product BG CO2 is used in combination with a mosquito suction trap placed outdoor (garden, terrace, etc.). The professional or non-professional user connects the gas canister to the mosquito trapping device, which then releases the carbon dioxide. No dermal, oral and inhalation exposure to the product is expected during this step.

Secondary exposure via inhalation to the general public present outside in the vicinity of the trapping device could occur. However, considering that there is a natural ventilation outdoors and thus around the trap, the exposure of the general public is considered very low.

To be noted that the active substance carbon dioxide presents a Community OEL of 9000 mg/m³. Since a Community OEL is derived from the average exposure of a professional during an 8-hour working day, it is not relevant for the general public.

Consequently, no personal protective equipment is required during the use of the product.

Conclusion

The product BG CO2 meets conditions of article 25 of the BPR for Human Health.

3.6.5 Dietary exposure

Not relevant. As carbon dioxide is listed in Annex I of Regulation (EU) No 528/2012 (category 6), a dietary risk assessment is not relevant.

3.7 Risk assessment for the environment

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the product fulfils all conditions for a simplified authorisation procedure.

3.7.1 Classification

Classification of the product has been calculated according to the classification rules for mixtures according to CLP Regulation (EC) N° 1272/2008 and the product is not classified for environment. The active substance is listed in Annex I of Regulation (EU) No 528/2012 without any restriction for the environment and there is no need for risk mitigation measure to protect the environment.

3.7.2 Substance(s) of concern

The product BG CO2 does not contain any environmental substance of concern (SoC) according to the EU guidance on SoC (Article 3(f) of the BPR, Guidance on BPR, Volume IV, Part B+C, version 2.0-2017).

3.7.3 Conclusion

The product BG CO2 meets conditions of article 25 of the BPR for the environment.

3.8 Assessment of a combination of biocidal products

Not relevant.

3.9 Comparative assessment

Not relevant, none of the active substance are candidate for substitution or exclusion.

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Not relevant.

4.1.2 Dietary assessment

Not relevant.

4.1.3 Environment

Not relevant.

4.2 New information on the active substance(s) and substance(s) of concern

Not relevant.

4.3 List of studies for the biocidal product

See IUCLID[List the studies by Reference No (Annex III requirement)/IUCLID Section Number and within a section alphabetically by author.]

Table 4.1 List of studies for the biocidal product

Author(s)	Year	Title Reference type Report and/or Study No. Source or Testing facility, if different from Sponsor	Study sponsor	IUCLID section (endpoint)	IUCLID document name	GLP	Data protection claimed
		Storage Stability of Carbon Dioxide Other company data <i>Report and Study No. not provided</i> <i>Source and/or Testing facility not provided</i>	<i>Study sponsor not provided</i>	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Storage stability tests - 3.4.1.2 Long term storage test at ambient temperature (waiver)	GLP information not provided	no

[REDACTED]	[REDACTED]	Confirmation of the stability of compressed carbon dioxide Other company data <i>Report and Study No. not provided</i> [REDACTED]	<i>Study sponsor not provided</i>	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Storage stability tests - 3.4.1.2 Long term storage test at ambient temperature (waiver, additional information)	GLP information not provided	no
[REDACTED]	[REDACTED]	The effect of adding carbon dioxide from pressurized gas cylinders to mosquito traps using the BG-Booster CO2 set on mosquito catch numbers. Study report Report No.: No report number [REDACTED]	[REDACTED]	6.7 Efficacy data to support these claims (efficacy data)	Efficacy data to support these claims.001 Field trial_Rose (2021)	no	yes

4.4 References

4.4.1 References other than list of studies for the biocidal product

4.4.2 Guidance documents

4.4.3 Legal texts

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.