

Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

**Carbon dioxide generated from propane, butane or a mixture of both
by combustion**

Product-type: 19

ECHA/BPC/249/2020

Adopted 16 June 2020

Opinion of the Biocidal Products Committee

on the application for approval of the active substance carbon dioxide generated from propane, butane or a mixture of both by combustion for product-type 19

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product-type 19 of the following active substance:

Common name:	Carbon dioxide generated from propane, butane or a mixture of both by combustion
Chemical name:	Carbon dioxide
EC No.:	204-696-9
CAS No.:	124-38-9
Existing active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Woodstream Corporation on 2 May 2008, the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to ECHA on 18 September 2019. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-35) and its Working Groups (WG I 2020). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the approval of the active substance carbon dioxide generated from propane, butane or a mixture of both by combustion in product-type 19 was adopted on 16 June 2020.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at: <http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval>.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the carbon dioxide generated from propane, butane or a mixture of both by combustion in product-type 19 may be approved.

The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of carbon dioxide generated from propane, butane or a mixture of both by combustion in product-type (PT) 19. The in-situ carbon dioxide generating device is intended to be used by the general public for outdoor use only. Carbon dioxide acts by attracting mosquitoes and other biting and nuisance insects by 'raised levels' of carbon dioxide. 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.

Specifications for the reference source are established: for in-situ substances, the reference specification is not based on the active substance generated but on the precursor. Here the precursors come from the open market and are considered as commodity chemicals. In consequence, no specification for the precursors is defined.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Analytical methods for the determination of carbon dioxide and impurities are available and considered as acceptable.

Carbon dioxide, is also approved as food additive under the Regulation (EC) 1333/2008 (as E290 in Regulation (EU) 1129/2011) as well as plant protection product under Regulation (EC) 1107/2009, which is currently under renewal. Moreover, carbon dioxide, is also used in medicine and cosmetic areas. Finally, carbon dioxide is already approved in the context of Regulation (EU) No 528/2012 (BPR) for PT 14 (rodenticide), PT 15 (avicide) and PT 18 (insecticide) uses, and listed in Annex I, category 6 of the BPR.

There is no harmonized classification available for carbon dioxide. No classification and labelling is proposed for carbon dioxide according to CLP regulation 1272/2008, given the lack of critical endpoints in terms of adverse effects on human health, on environment and when considering the physico-chemical properties.

Due to the intended use by the general public, the only requirement for labelling of the device is "Only use for outdoor application".

b) Intended use, target species and effectiveness

Carbon dioxide is used as an insect attractant for PT 19, especially to attract mosquitoes. Carbon dioxide generated from propane, butane or a mixture of both by combustion is used through a special device by general public, and will be placed outdoor.

Submitted data are sufficient to demonstrate the efficacy of carbon dioxide for active substance approval. The representative device, using carbon dioxide (generated from propane by combustion), attracts mosquitoes (such as *Aedes* spp., *Anopheles* spp. and *Culex* spp.) at a release rate of 500 mL/min.

No resistance has been detected in any flying insect species, which is attracted to carbon dioxide.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

The table below summarizes the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	Primary or secondary exposure and description of scenario	Exposed group	Conclusion
Loading of the precursors	<i>Primary exposure</i> The device uses gas cylinders such as those used for camping and cooking. The gases are supplied in sealed cylinders or reusable gas bottles which are typically supplied as snap-lock fitting and are compliant with international standards for gas burning appliances. They release gas into the burner only when fitted into the generators.	General public	Acceptable
Cleaning or maintenance of application equipment	<i>Primary exposure</i> Cleaning or maintenance, such as emptying the traps, would typically require the closing of the carbon dioxide source, therefore there is no expected exposure to carbon dioxide when cleaning or maintaining equipment. However, at a worst case the operator can be exposed at a release rate of 500 ml/min of carbon dioxide. This scenario is covered by the scenario of a person which is passively exposed to carbon dioxide issued from the device.	General public	Acceptable
Indirect exposure (outdoor)	<i>Secondary exposure</i> A person in the vicinity of the device may be exposed to carbon dioxide released.	General public	Acceptable

Carbon dioxide is a gas occurring ubiquitously in the atmosphere. The body produces large volumes of carbon dioxide as a result of normal metabolic processes and excretes it by expiring. At rest, the body's metabolism produces approximately 200 ml of carbon dioxide per min, whilst when exercising vigorously it can increase this volume 10 times. The process of production, transport and excretion of carbon dioxide in humans is well known, as its toxicity profile.

The use of carbon dioxide as an attractant leads to acceptable risk for general public.

The device requires the following labelling: "Only use for outdoor application".

Environment

Carbon dioxide occurs naturally in the environment at approximately 0.04% in the atmosphere. In air, the local concentration of carbon dioxide is expected to be increased due to the use of the releasing units. Under real use conditions (outdoor uses), the produced carbon dioxide would be affected by loss mechanisms such as dissipation by environmental factors such as wind force and direction. In water, any local increase of dissolved carbon dioxide is counteracted by an equilibrium that exists between the carbon dioxide found naturally in the water and the air. This equilibrium means that the aquatic concentrations of carbon dioxide remain constant, at the level found naturally in the environment. Under normal conditions of use, there will be no direct exposure of carbon dioxide to the terrestrial environment. Any carbon dioxide which could diffuse into the terrestrial compartments will be incorporated into the natural carbon cycle. At last, carbon dioxide releasing units are intended for outdoor use only and carbon dioxide will therefore not enter sewage treatment plants.

The intended use of carbon dioxide as an attractant (outdoor use only) will not affect the levels of carbon dioxide found naturally in the environment. Therefore, no unacceptable risks are expected for the environmental compartments. Similarly, the emissions of carbon dioxide due to this use are very low, and the contribution to global warming, ozone formation in the troposphere or to acidification is negligible. At last, carbon dioxide does not have any intrinsic properties, which suggest that it will bioaccumulate in the environment.

Overall conclusion

A safe use for human health and environment is identified for the following scenarios: loading of the precursors, cleaning or maintenance of application equipment and indirect exposure for a person in the vicinity of the device releasing carbon dioxide.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	No classification required	Carbon dioxide generated from propane, butane or a mixture of both by combustion does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P or vP	Carbon dioxide generated from propane, butane or a mixture of both by combustion does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	not T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	Carbon dioxide generated from propane, butane or a mixture of both by combustion does not fulfil criterion (d) of Article 5(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No	
	Article 57(f) and 59(1) of REACH	No	

	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required		
Concerns linked to critical effects other than those related to endocrine disrupting properties	Carbon dioxide generated from propane, butane or a mixture of both by combustion does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Carbon dioxide generated from propane, butane or a mixture of both by combustion does not fulfil this criterion.		

Consequently, the following is concluded:

Carbon dioxide does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Carbon dioxide does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

The exclusion and substitution criteria were assessed in line with the “Note on the principles for taking decisions on the approval of active substances under the BPR”¹, “Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR”² and on the application of the substitution criteria set out under article 10(1) of the BPR”³ and “Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment”⁴ agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f). The exclusion criterion (d) was assessed in line with the criteria laid down in the Annex of Regulation (EU) No 2017/2100, which apply as of 7 June 2018.

2.2.2. POP criteria

Carbon dioxide does not fulfil criteria for being a persistent organic pollutant (POP).

¹ See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from <https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc>)

² See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from [https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10\(1\).doc](https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc))

³ See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from [https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10\(1\).doc](https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc))

⁴ See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment (<https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx>).

2.3. BPC opinion on the application for approval of the active substance carbon dioxide generated from propane, butane or a mixture of both by combustion in product type 19

In view of the conclusions of the evaluation, it is proposed that carbon dioxide generated from propane, butane or a mixture of both by combustion shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. The active substance is carbon dioxide generated from propane, butane or a mixture of both by combustion. The precursors propane and butane come from the open market and are considered as commodity chemicals. In consequence, no specification for the precursors is defined.
2. The authorisations of biocidal products are subject to the following condition(s):
 - a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

The active substance carbon dioxide generated from propane, butane or a mixture of both by combustion fulfils the criteria according to Article 28 (1) to enable inclusion in Annex I of Regulation (EU) No 528/2012.

2.4. Elements to be taken into account when authorising products

The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

- a. It should be demonstrated that the active substance generated in-situ by any device is < 400 ppm at 1 m distance from the device, corresponding to the natural occurrence of the substance in the air. The compliance with the specification of the active substance has to be demonstrated when submitting an application for product authorisation, according to the revised Recommendation of the BPC Working Groups "In situ generated active substances – Risk assessment and implications on data requirements for active substances generated in situ, their precursors and biocidal products".

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of carbon dioxide generated from propane, butane or a mixture of both by combustion.