

Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Carbon dioxide

Product-type: 15

ECHA/BPC/016/2014

Adopted

17 June 2014

Opinion of the Biocidal Products Committee

on the approval of the biocidal active substance carbon dioxide for product type 15

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, the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product-type 15 of the following active substance:

Common name: Carbon dioxide

Chemical name: Carbon dioxide

EC No.: 204-696-9

CAS No.: 124-38-9

Existing active substance submitted under Article 11 of the Biocidal Products Directive 98/8/EC.

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

Process for the adoption of opinions

Following the submission of an application by Duke Faunabeheer on 22 February 2012, the evaluating Competent Authority (The Netherlands) submitted an assessment report and the conclusions of its evaluation to the Commission on 30 August 2013. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC member for the Netherlands

The BPC opinion on the approval of the active substance carbon dioxide in product-type 15 was adopted on 17 June 2014.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that carbon dioxide in product-type 15 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. Opinion

2.1. Conclusions of the evaluation

a) Presentation of the active substance and representative biocidal product including classification of the active substance

This evaluation covers the use of carbon dioxide in product -type 15. Carbon dioxide acts by "respiratory acidosis" in target animals, leading to unconsciousness, minimal brain activity, ineffective heartbeat and ultimately death. Specifications for the reference source are established.

Carbon dioxide and the biocidal product (which is the same as the active substance) do not exhibit any particularly hazardous physical-chemical properties, and users are not considered to be at risk due to the physical-chemical properties of this active substance and the biocidal product.

No validated analytical methods were submitted for the determination of carbon dioxide in soil, tap water and surface water and in air, which due to the nature of the carbon dioxide is considered acceptable as no monitoring is to be expected.

There is no harmonised classification available for carbon dioxide. No classification and labelling is proposed for carbon dioxide, given the lack of critical endpoints in terms of adverse effects on human health and of physico-chemical properties. There is an extensive database of information available on carbon dioxide. No critical end points in terms of adverse effects on the environment have been identified for carbon dioxide.

Classification according to Regulation (EC) No 1272/2008 (CLP Regulation)	
Hazard Class and Category Codes	Pres. Gas. H280
Labelling	
Pictograms	GHS04
Signal Word	Warning
Hazard Statement Codes	H280: contains gas under pressure; may explode if heated
Specific Concentration limits, M-Factors	Not applicable.

b) Intended use, target species and effectiveness

Carbon dioxide is to be used by professional pest control officers for killing nuisance birds.

The data on carbon dioxide and the representative biocidal product (which is the same as the active substance) have demonstrated sufficient efficacy against geese. The representative product is intended to be used for the control of geese around airports in order to improve aviation safety and should be used as part of an integrated pest management (IPM) strategy. IPM, can involve the growing of less attractive crops to geese in the vicinity of airports; after the harvest removing all the remnants of the crops or covering these immediately; installing special radar equipment to detect geese flying

in the surroundings; the use of big bird predators.

When carbon dioxide is used against geese (exposed to 70-90% v/v carbon dioxide for 5 minutes in an air tight container) efficacy was demonstrated. Unconsciousness in geese was observed within 1 minute and ineffective heart function within 5 minutes from the beginning of treatment. The test resulted in 100% mortality of the geese. Because of the fast action (unconsciousness within one minute), the special shape of the container (low roof) and the very fast filling of the container with CO₂ to a concentration of 70-90% (within one minute), this use of carbon dioxide is not considered to cause unnecessary pain and suffering to birds.

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

Human health

The toxicological assessment shows that by using the appropriate safety measures (detailed in section 2.4 of this opinion) exposure to professional users to carbon dioxide when used as avicide is considered to be negligible, and safe use can be concluded. Personal protective equipment (PPE) (self-contained breathing apparatus) is necessary in the rare occasion that the professional needs to enter the container when the concentration is above 1.5%.

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

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

Environment

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

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

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

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

Similarly for the terrestrial and atmospheric environmental compartments, there will be no increase in the levels of carbon dioxide in the atmosphere or soil outside normal atmospheric ranges from the use of carbon dioxide as an avicide. The ecotoxicological assessment shows that environmental natural concentrations are not affected by the use of carbon dioxide as avicide and there are no critical endpoints in terms of adverse ecotoxicological effects. The evaluation has concluded that under the proposed normal conditions of use, there are no unacceptable effects on the environment or wildlife.

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		Classification
CMR properties	Carcinogenicity (C)	no classification required
	Mutagenicity (M)	no classification required
	Toxic for reproduction (R)	no classification required
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P and not vP
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B and not vB
	Toxic (T)	not T
Endocrine disrupting properties	not considered to have endocrine disrupting properties	

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" agreed at the 54th meeting 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 ([CA-March14-Doc.4.1 - Final - Principles for the approval of AS.doc](#)). This implies that the assessment of the exclusion criteria is based on Article 5(1) using the temporary criteria for the determination of endocrine-disrupting properties in Article 5(3) and the assessment of substitution criteria is based on Article 10(1)(a, b and d).

2.2.2. POP criteria

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.

2.3. BPC opinion on the application for approval of the active substance carbon dioxide in product-type 15

In view of the conclusions of the evaluation, it is proposed that carbon dioxide shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of carbon dioxide is 999 ml/l
2. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
3. Products shall only be sold to and used by professionals trained to use them.
4. Appropriate measures to protect operators shall be taken to ensure minimum risk, including the availability of personal protective equipment (PPE) if necessary.
5. Appropriate measures shall be taken to protect bystanders such as exclusion from the treatment area.
6. Conditions shall be set to obtain sufficient efficacy, without unnecessary pain and suffering to the birds.
7. Carbon dioxide shall be used as a biocide as part of an Integrated Pest Management (IPM) strategy.

The active substance does fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012. However, due to the fact that the biocidal product can only be used by professionals trained to apply special measures, and use PPE when necessary, it is not recommended to include CO₂ for product type 15 in Annex I. Moreover, Union authorisations are not possible for product type 15 (Article 42(1) of Regulation (EU) No 528/2012).

2.4. Elements to be taken into account when authorising products

To ensure proper efficacy for geese, the following use instructions should be taken into account:

1. the carbon dioxide flow into the container should be of such volume that the required concentration of 70-90% CO₂ is reached within 1 minute,
2. this concentration should be kept for at least 5 minutes,
3. to make sure these conditions are reached the gas concentration in the container should be (on-line) monitored by means of a carbon dioxide meter.

To ensure safe use, the following safety measures should be taken into account:

1. proper venting of the container used for killing of the 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.

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.

When at product authorisation the label claim includes other birds than geese, for each claimed bird species, or group of species, new efficacy studies should be provided to ensure that for each species unnecessary pain and suffering is avoided.