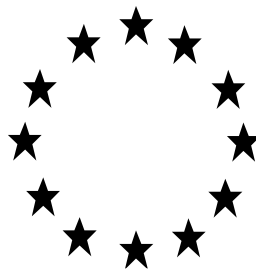


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the competent authority)



EKOMILLE CO₂

Product type 14

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

Case Number in R4BP: BC-LJ068510-40

Competent Authority: IT

Date: 01 April 2022

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Note to the reader

This amended version of the PAR is based on the outcome of the discussion within the Coordination Group (CG) following formal referral. The amended parts are in the track changes version.

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	IT	BC-LJ068510-40		Initial assessment	
SA-APP	IT	BC-LJ068510-40 / EU-0027206-0000	12/01/2023 (outcome of referral)	Amendment post referral	1/5,6 2.2/8 3.5.1/19 3.5.2/19 3.5.4/23

1 Conclusion

EKOMILLE CO₂ is a ready-to-use gas canister functioning together with a trapping device containing carbon dioxide as active substance. The product is used as a rodenticide accompanying method (PT14) to control roof rat (*Rattus rattus*) in and around buildings, open areas and waste dumps by trained professional users.

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 uses as rodenticide by trained professionals, 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 substance Carbon dioxide is listed in Annex I of Regulation (EU) 528/2012 and satisfy the restriction "Only for use in ready-for-use gas canisters functioning together with a trapping device";
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 should be considered not to have endocrine-disrupting properties.

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 manufacturer 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. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer of the active substance is listed in section 1.5 of the SPC.

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.

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

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 and respective characteristics

Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

A physical hazard was identified. Contains gas under pressure; may explode if heated. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Please refer to the Assessment report for the active substance Carbon dioxide (PT 14) Finalised in the Standing Committee on Biocidal Products at its meeting on 29 November 2007 in view of its inclusion in Annex I & IA to Directive 98/8/EC.

Efficacy against target organisms

The biocidal product has been shown to be efficacious as an accompanying method against house rats (*Rattus rattus*) for all intended uses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

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

Dietary risk assessment

Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Risk assessment for animal health

Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Risk assessment for the environment

Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Post-authorisation conditions

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Table 1.1 Post-authorisation conditions

Description	Due date
-	-

2 Information on the biocidal product

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

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

Product type	PT14
Type of formulation	Gas canister associated with a trapping device

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	Rodenticide (Accompanying method)	PT14	<i>Rattus rattus</i>	Gas canister functioning together with a trapping device	1 canister for 10 captured units	Trained Professionals	A	In public areas it must be clearly signed that rodenticide control is in operation. Signage must provide information on the risks of interfering with the product

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 categor(y/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 identity and composition of the biocidal product are

identical
 not identical

to the identity and composition of the product evaluated in connection with the inclusion of the active substance in category 6 of Annex I of Regulation (EU) No 528/2012.

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

Table 2.3 Identity of the active substance

Main constituent	
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	Not applicable
Minimum purity / content	≥99.99%
Structural formula	O=C=O

2.5 Information on the source of the active substance

Is the source of Carbon dioxide the same as the ones evaluated in connection with the inclusion of the active substance in category 6 of Annex I of Regulation No. 528/2012?

Yes
 No

2.6 Candidate for substitution

Not applicable.

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 biocidal product.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

	Classification	Labelling
Hazard Class and Category code	Press. Gas (Comp.)	
Hazard Pictograms	GHS04: gas cylinder	GHS04
Signal word(s)	Warning	Warning
Hazard statements	H280 – Contains gas under pressure; may explode if heated	Contains gas under pressure; may explode if heated
Precautionary statements*	P410+P403 : Protect from sunlight. Store in a well-ventilated place	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

In accordance with Article 20(1)(b) of the BPR a LoA is not required, even if the AS is listed under category 6.

2.10 Data submitted in relation to product authorisation

No new data on the active substance has 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 Canister	350 g (diameter 70 mm, height 213 mm)	Carbon steel	-	Trained 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

Since the active substance and the product are identical, physical, chemical and technical properties of the active substance is also applicable for the product EKOMILLE CO₂.

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	-	-	-	-
3.1.1.	Physical state at 20 °C and 101.3 kPa	-	Gaseous	-	
3.1.2.	Colour at 20 °C and 101.3 kPa	-	-	Colourless	Assessment report for the active substance Carbon dioxide (PT 14)
3.1.3.	Odour at 20 °C and 101.3 kPa	-	-	Odourless	Assessment report for the active substance Carbon dioxide (PT 14)
3.2.	Acidity, alkalinity and pH value	-	-	-	-
3.3.	Relative density / bulk density	1.527 (where air = 1). Purity of carbon dioxide not available. The density is 1.977 g/l at 0°C			Assessment report for the active substance Carbon dioxide (PT 14)
3.4.1.1.	Storage stability test – accelerated storage			No stability study is provided to demonstrate the stability of product. Nevertheless carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage.	
3.4.1.2.	Storage stability test – long-term storage at ambient temperature			No stability study is provided to demonstrate the stability of product. Nevertheless carbon dioxide is a	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				thermodynamically stable compound which is not expected to degrade on storage.	
3.4.1.3.	Storage stability test - low temperature stability test for liquids			No stability study is provided to demonstrate the stability of product. Nevertheless carbon dioxide is a thermodynamically stable compound which is not expected to be affected during low temperature storage.	
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product - light			The product contains 100% of carbon dioxide compressed in a metal canister. There is no effect from light.	
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product - temperature and humidity			The product contains 100% of carbon dioxide compressed in a metal canister. There is no effect from temperature and humidity.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material			The product contains 100% of carbon dioxide compressed in a canister (metal: steel). Carbon dioxide is not known to be corrosive to metal.	

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

The product EKOMILLE CO₂ is a ready-to-use gas canister functioning together with a trapping device containing carbon dioxide as active substance.

EKOMILLE CO₂ contains 100% carbon dioxide in gas canister. No stability study is provided to demonstrate the stability of product. Nevertheless carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage. In consequence, IT CA proposed a shelf life of 2 years.

Its technical characteristics are acceptable for a gas formulation.

Implications for labelling: None

3.3 Physical hazards and respective characteristics

Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Since the active substance and the product are identical, physical hazards and respective characteristics of the active substance is also applicable for the product EKOMILLE CO₂.

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
4.1.	Explosives	It is widely accepted that carbon dioxide is thermodynamically stable and therefore does not exhibit explosive properties		
4.2.	Flammable gases	Non flammable		
4.3.	Flammable aerosols	Not relevant as the product contains 100% of carbon dioxide compressed in a canister, which is not known to be a flammable substance		
4.4.	Oxidising gases	It is widely accepted that carbon dioxide is thermodynamically stable and therefore does not exhibit oxidising properties, even if it could be tested		
4.5.	Gases under pressure	The product is a ready-to-use compressed gas		
4.16.	Corrosive to metals	Carbon dioxide is not known to be corrosive to metal		

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is classified as Press. Gas; H280; contains gas under pressure; may explode if heated.

3.4 Methods for detection and identification

Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Please refer to the Assessment report for the active substance Carbon dioxide (PT 14) Finalised in the Standing Committee on Biocidal Products at its meeting on 29 November 2007 in view of its inclusion in Annex I & IA to Directive 98/8/EC.

Table 3.6 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification

According to the the Assessment report for the active substance Carbon dioxide (PT 14) Finalised in the Standing Committee on Biocidal Products at its meeting on 29 November 2007 in view of its inclusion in Annex I & IA to Directive 98/8/EC, the infra-red method for analysing the active substance, as manufactured, has been validated and shown to be sufficiently specific, accurate and precise. It can be used for analysis of carbon dioxide in air. In contrast, it has not been considered necessary to submit analytical methods in environment matrices because the exposure assessment has shown that there is no mechanism for carbon dioxide to be released directly into soil or water because it is a gas.

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)

EKOMILLE CO₂, a ready-to-use compressed gas in a canister containing 100% of carbon dioxide, is intended to be used as an accompanying method to control roof rat (*Rattus rattus*) in and around buildings, open areas and waste dumps by trained professional users. Each canister contains 350 g of carbon dioxide for use in trapping device. It guarantees a maximum of 10 catches. Ekonomie CO₂ has an upper section for access and capture and a lower section for containment and suppression of the captured species, hermetically closed. Rodents are attracted by food and enter inside the device. The electromechanical system with a rotating trap-door, interposed between the two sections, is activated by a presence detection sensor (located in the upper section) and is connected to a CO₂ gas supply system, which delivers a quantity of gas after each capture, immediately after closing the trap-door. The specific characteristics of the canister do not require additional control equipment such as: pressure gauge, pressure reducer, indicator valve, solenoid valve. The system does not require adjustment. The timer inserted in the electronic circuit is set in the factory for a delivery time of 5 seconds. This allows enough quantities of CO₂ able to reach a concentration higher than 60% and suppress the trapped pest rodent, in combination with the liquid in the lower compartment, in less than a minute. Once the capture has taken place, the device automatically positions itself in stand-by, ready for a new capture. The CO₂ canister guarantees a maximum of 10 catches. The device is equipped with an electronic counting system that only allows 10 acquisitions so that after the tenth catch, the device goes into stand-by and no other captures are possible until reset by the user. When setting up the device, the lower compartment has to be filled with 18 L of liquid (e.g., Ekofix100 dilution, water). The device must not be used without liquid. Only liquids that have no toxic effect on the rodents and that allow the rodent to swim (comparable uplift like water) are allowed to be used with the device. It must be ensured that there is always a sufficient amount of liquid in the trap (liquid must not freeze and evaporated amounts must be replenished). The liquid used in the tests and envisaged by the instructions for use consists of a hydroalcoholic mixture made up of water (13 l) and Ekofix100 (5 l). The mixture has no toxic effects on the rodent and its density is comparable to water. The traps should be filled with bait. Pre-bait the device without activating the catch mechanism. If the bait is not accepted, choose a more suitable bait. The traps should be visited at regular intervals in order to check the bait in the trap and refill it if needed.

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

Rodents are attracted by food and enter inside the device where they are caught and fall into a compartment partially filled with a liquid. At the same time, carbon dioxide is released into the compartment by the canister. Rodents will lose consciousness by inhaling carbon dioxide. The CO₂, in direct contact with the captured rodent, first puts it to sleep, then it faints and immediately afterwards, absolutely unconscious, is painlessly suppressed. The suppression, therefore, occurs by hypoxia, within a very short time, through depression of the central nervous system.

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
PT14 Use 1: Rodenticide	EKOMILLE CO ₂	Rodenticide	<p>A laboratory test was performed to demonstrate that the CO₂ gas concentration in the trap is efficient enough to kill pests (<i>Mus musculus</i>, <i>Rattus rattus</i> and <i>Rattus norvegicus</i>) based on literature data. The results obtained do not depend on the temperature.</p> <p>The test was performed in three sites that were chosen to evaluate the behaviour of the trap at different temperatures.</p> <p>Site A): Room at 30°C and 43% RH Site B): Room at 21°C and 49% RH Site C): outdoor site at 17°C and 67% RH</p> <p>To measure the concentration of CO₂ reached into the trap EKOMILLE CO₂, the time to reach the maximum concentration and the time a sufficient concentration of CO₂ is maintained for enough time to be effective in killing the rodents.</p>	<p>CO₂ is released in 5 seconds and therefore this is the time the maximum concentration is reached.</p> <p>The minimum concentration of CO₂ reached was 80%. The maximum was 86%.</p> <p>The lowest concentration of CO₂ recorded after 8 minutes since the starting of the sub-replication (emission of the gas) was 60%. The highest was 74%.</p> <p>The conclusion is that any rodent captured by the trap is kept for at least 8 minutes at a concentration of CO₂ > 60%. This value, which ensure the rapid dead of all the animals, is not affected by the temperature which can be encountered during a normal use.</p>	Drago A. 29 April 2021	6.1 doc.02_EKO Q074A-21 ekomille co2 290421 def 2021- 07-07
PT14 Use 1:	EKOMILLE CO ₂	Roof rat	The tests were conducted in a small private stable intended for the breeding of	The data collected by the three different traps were	Drago A. 27	

Rodenticide		<i>(Rattus rattus)</i>	<p>farmyard animals (laying hens and rabbits) severely infested by roof rat (<i>Rattus rattus</i>). To perform the test 3 Ekomille CO₂ traps have been used. Ekomille 1 and Ekomille 2 were placed October 15, 2021 and kept off to overcome the rodent neophobia, and were checked to verify that the animals were going to eat up to the manger where the sensor is present. On October 18, when rodents had entered the machines, the devices were turned on for capture and killing. As soon as the desired number of catches was reached, Ekomille 1 was replaced with Ekomille 3 on 20 October. Recorded videos were exported in .avi format and observed for rodent killing verification.</p>	<p>very homogeneous as never the time to kill a rat was above the threshold of 30 seconds. The results obtained are in line with the data reported by the international scientific bibliography, already listed in the report Entostudio 29 April 2021. At the end of the experiment, the population of <i>Rattus rattus</i> initially present in the stable was completely eradicated.</p> <p>The results obtained are in line with the bibliography analysis and conclusion reported in the study report (doc.02_EKO Q074A-21 ekomille co2 290421 def 2021-07-07)</p>	December 2021	
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3.5.4 Efficacy assessment

The efficacy of the product was tested through a laboratory study (Drago, April 2021) and a field study (Drago, December 2021).

The laboratory study was performed to demonstrate that the CO₂ concentration in the trap is efficient enough to kill rodents. The time concentrations of CO₂ into the traps were measured. The results of the study show that the concentration of CO₂ released by the device is high enough (80%) to lead a quick loss of consciousness of the animals followed by death.

The second study was conducted in a small private stable severely infested by roof rat. Three Ekomille CO₂ traps were used. No proper population census was performed.

The CG members agreed by consensus on 12 January 2023 that the field study (Drago, December 2021) is suitable to demonstrate the efficacy of the product as an accompanying method to control roof rat (*Rattus rattus*).

3.5.5 Conclusion on efficacy

The biocidal action of carbon dioxide is primarily due to it causing "respiratory acidosis" in target animals. Once released, the carbon dioxide reaches the maximum concentration of 86% within 5 seconds; and 8 minutes later on, declines to approximately 60%. Thus, any rodent captured by the trap is kept for at least 8 minutes at a concentration of CO₂ > 60%. This value, which ensure the rapid dead of all the animals, is not affected by the temperature which can be encountered during a normal use. The inhalation of concentrations of CO₂ higher than 60% is known to act as an anaesthetic and leads to a rapid loss of consciousness. In most publications, it is recommended to place the animal into a concentration of CO₂ higher than 70% to obtain quick loss of consciousness, followed by death of the animals. IT competent authority (IT-CA) considers that the elements presented in the dossier support the efficacy of EKOMILLE CO₂ as an accompanying method to control roof rat (*Rattus rattus*) by trained professional users.

3.5.6 Occurrence of resistance and resistance management

The development of resistance to carbon dioxide is not possible because, when it is used as a biocide, it will be lethal to the target rodent in a single dose. Killing the target rodent in a single dose means that no mechanism for resistance to carbon dioxide can be developed because target organisms are never exposed to sub-lethal concentrations of carbon dioxide, unlike the multi-feed pesticides such as anticoagulant rodenticides.

3.5.7 Known limitations

No limitations on efficacy are known.

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

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

3.6 Risk assessment for human health

A full risk assessment for human health is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

The product does not contain any substance of concern (SoC) and its application does not require the use of protective personal equipment (PPE).

In public areas it must be clearly signed that rodenticide control is in operation. Signage must provide information on the risks of interfering with the product.

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

No substances of concern regarding human health were identified.

3.6.2 Other

Not relevant.

3.6.3 Available toxicological data relating to endocrine disruption

No indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the biocidal product.

3.7 Risk assessment for animal health

A risk assessment for animal health is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.8 Risk assessment for the environment

A full risk assessment for the environment is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.8.1 Substance(s) of concern

The product does not contain any substance of concern (SoC) for the environment.

3.9 Assessment of a combination of biocidal products

Not relevant.

3.10 Comparative assessment

Not relevant.

EKOMILLE CO₂ does not contains any active substances that is a candidate for substitution.

4 Appendices

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

No new information on the active substance is available.

4.2 List of studies for the biocidal product

Table 4.1 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. (Annex III requirement) / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
█	2021	6.1	doc.02_EKO Q074A-21 ekomille co2 290421 def 2021-07-07	Measurement of CO ₂ in Ekomille to kill trapped rodents	Study report	Entostudio S.r.l.	No	Yes
█	2021	6.1	EKO ekomille co2 Rr 271221 REPORT	Efficacy of ekomille co2 in killing black rat <i>Rattus rattus</i> in field conditions	Field Study report	Entostudio S.r.l.	No	Yes
█	2021	13	doc.01_Ekomille.Co2.description.rev.04.20 21-07-07	Ekomille with CO ₂ method of suppression for rodent control with no pain	Product description	Apice S.r.l.	No	Yes

4.3 References

4.3.1 References other than list of studies for the biocidal product

- Assessment report for the active substance Carbon dioxide (PT 14), 21 June 2007.

4.3.2 Guidance documents

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4.3.3 Legal texts

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

4.4 Confidential information

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