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

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

(submitted by the evaluating Competent Authority)



RADAR

Product type 14

Carbon dioxide as included in the Annex I of the Biocidal Products Regulation (BPR)

Case Number in R4BP: BC-MF049778-24

Evaluating Competent Authority: FR CA

Date: [day/month/year]

Table of Contents

[Table of Contents 2](#_Toc21333533)

[*1* CONCLUSION 4](#_Toc21333534)

[*2* ASSESSMENT REPORT 6](#_Toc21333535)

[2.1 Summary of the product assessment 6](#_Toc21333536)

[2.1.1 Administrative information 6](#_Toc21333537)

[**2.1.1.1** Identifier of the product 6](#_Toc21333538)

[**2.1.1.2** Authorisation holder 6](#_Toc21333539)

[**2.1.1.3** Manufacturer(s) of the products 6](#_Toc21333540)

[**2.1.1.4** Manufacturer(s) of the active substance(s) 6](#_Toc21333541)

[2.1.2 Product composition and formulation 7](#_Toc21333542)

[**2.1.2.1** Identity of the active substance 7](#_Toc21333543)

[**2.1.2.2** Candidate(s) for substitution 7](#_Toc21333544)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product 8](#_Toc21333545)

[**2.1.2.4** Information on technical equivalence 8](#_Toc21333546)

[**2.1.2.5** Information on the substance(s) of concern 8](#_Toc21333547)

[**2.1.2.6** Assessment of endocrine disruption (ED) properties of the biocidal product 8](#_Toc21333548)

[**2.1.2.7** Type of formulation 8](#_Toc21333549)

[2.1.3 Hazard and precautionary statements 8](#_Toc21333550)

[2.1.4 Authorised use(s) 9](#_Toc21333551)

[**2.1.4.1** Use description 9](#_Toc21333552)

[**2.1.4.2** Use-specific instructions for use 9](#_Toc21333553)

[**2.1.4.3** Use-specific risk mitigation measures 9](#_Toc21333554)

[**2.1.4.4** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 9](#_Toc21333555)

[**2.1.4.5** Where specific to the use, the instructions for safe disposal of the product and its packaging 9](#_Toc21333556)

[**2.1.4.6** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 10](#_Toc21333557)

[2.1.5 General directions for use 11](#_Toc21333558)

[**2.1.5.1** Instructions for use 11](#_Toc21333559)

[**2.1.5.2** Risk mitigation measures 11](#_Toc21333560)

[**2.1.5.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 11](#_Toc21333561)

[**2.1.5.4** Instructions for safe disposal of the product and its packaging 11](#_Toc21333562)

[**2.1.5.5** Conditions of storage and shelf-life of the product under normal conditions of storage 11](#_Toc21333563)

[2.1.6 Other information 11](#_Toc21333564)

[2.1.7 Packaging of the biocidal product 11](#_Toc21333565)

[2.1.8 Documentation 12](#_Toc21333566)

[**2.1.8.1** Data submitted in relation to product application 12](#_Toc21333567)

[**2.1.8.2** Access to documentation 12](#_Toc21333568)

[2.2 Assessment of the biocidal product 13](#_Toc21333569)

[2.2.1 Intended use(s) as applied for by the applicant 13](#_Toc21333570)

[2.2.2 Physical, chemical and technical properties 13](#_Toc21333571)

[2.2.3 Physical hazards and respective characteristics 21](#_Toc21333572)

[2.2.4 Methods for detection and identification 24](#_Toc21333573)

[Analytical methods for the active and impurities in the technical material 24](#_Toc21333574)

[2.2.5 Efficacy against target organisms 26](#_Toc21333575)

[**2.2.5.1** Function and field of use 26](#_Toc21333576)

[**2.2.5.2** Organisms to be controlled and products, organisms or objects to be protected 26](#_Toc21333577)

[**2.2.5.3** Effects on target organisms, including unacceptable suffering 26](#_Toc21333578)

[**2.2.5.4** Mode of action, including time delay 27](#_Toc21333579)

[**2.2.5.5** Efficacy data 27](#_Toc21333580)

[**2.2.5.6** Occurrence of resistance and resistance management 30](#_Toc21333581)

[**2.2.5.7** Known limitations 30](#_Toc21333582)

[**2.2.5.8** Evaluation of the label claims 30](#_Toc21333583)

[**2.2.5.9** Relevant information if the product is intended to be authorised for use with other biocidal product(s) 30](#_Toc21333584)

[The RADAR product is not intended to be used with another biocidal product. 30](#_Toc21333585)

[2.2.6 Risk assessment for human health 31](#_Toc21333586)

[2.2.7 Risk assessment for animal health 31](#_Toc21333587)

[2.2.8 Risk assessment for the environment 31](#_Toc21333588)

[2.2.9 Measures to protect man, animals and the environment 31](#_Toc21333589)

[2.2.10 Assessment of a combination of biocidal products 31](#_Toc21333590)

# CONCLUSION

***Intended uses***

RADAR is a ready-to-use compressed gas in a canister containing 100 % of carbon dioxide. It is intended to be used to control mice such as house mouse (*Mus musculus*) in areas where there is not a severe infestation of rodents. Each sparklet gas canister contains 2.8 g or 8 g of carbon dioxide for use in trapping devices.

***Physico-chemical properties and Analysis methods***

The active substance contained in the biocidal product RADAR (carbon dioxide) is listed in Annex I of EU Regulation 528/2012 and the biocidal product RADAR does not contain any nanomaterials.

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Carbon dioxide is a colourless and odourless gas. CO2 is a thermodynamically stable gas and therefore does not exhibit explosive properties. A storage stability study is not be scientifically justified. Following the same logic, no technical characteristics are necessary.

CO2 is not flammable and has no oxidising properties. Its relative density is 1.527.

Analytical method for the determination of the active substance in the formulation is available and validated.

***Efficacy***

French competent authorities (FR CA) considers that the elements presented in the dossier support the efficacy of the 2,8 and 8 g sparklet gas canister, for use indoors in trapping devices against house mice (Mus musculus) by professional users.

***Human health***

The active substance is not classified as hazardous to the human health under Reg. (EC) 1272/2008. The product is thus not classified for the human health. Moreover, the product does not contain any any co-formulant.

Therefore no SOCs for the human health are considered to be present in the RADAR product.

***Environment***

The active substance is not classified as hazardous to the environment under Reg. (EC) 1272/2008. The product is thus not classified for the environment. Moreover, the product does not contain any co-formulant.

Therefore no SOCs for the environment are considered to be present in the RADAR product.

**GENERAL CONCLUSION: Eligibility for the simplified authorisation procedure**

Following evaluation, the biocidal product RADAR does meet the conditions required for simplified authorisation as defined in Article 25 of 528/2012, i.e.:

1. The active substance carbon dioxide is listed in Annex I of Regulation (EU) 528/2012 and satisfies the restriction that the product is only for use in ready-for-use gas canisters functioning together with a trapping device.

2. The biocidal product does not contain any substances of concern according to the definition described in article 3 (f) of the BPR.

3. The biocidal product does not contain any nanomaterials.

4. The use pattern and associated label claims of the biocidal product have been judged sufficiently effective.

5. The handling of the biocidal product as part of its intended use does not require any PPE.

**Therefore, FR CA considers that the biocidal product shall be authorized.**

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
|  | RADAR |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Rentokil Initial 1927 plc |
| **Address** | Power Centre, Unit A1 & A2,  Link 10 Napier Way  RH10 9RA Crawley  United-Kingdom |
| **Authorisation number** | **FR-2009-0001** | |
| **Date of the authorisation** | **14/10/2019** | |
| **Expiry date of the authorisation** | **13/10/2029** | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | Rentokil Initial Supplies |
| **Address of manufacturer** | Weber Road, Knowsley Industrial Park L33 7SR Kirkby, Merseyside United Kingdom |
| **Location of manufacturing sites** | Weber Road, Knowsley Industrial Park L33 7SR Kirkby, Merseyside United Kingdom |
| Svitavská 1607/62, 571 01, Moravská Třebová - Czech Republic |
| Oude Dijk 1 Blokveld 21 - 9130 Kallo - Belgium |
| Rua Comendador Arlindo Soares de Pinho, 1977 3730-423 Vale de Cambra - Portugal |

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

|  |  |
| --- | --- |
| **Active substance** | Carbon dioxide |
| **Name of manufacturer** | Rentokil Initial Supplies |
| **Address of manufacturer** | Weber Road, Knowsley Industrial Park  L33 7SR Kirkby, Merseyside  United Kingdom |
| **Location of manufacturing sites** | Weber Road, Knowsley Industrial Park  L33 7SR Kirkby, Merseyside  United Kingdom |

### Product composition and formulation

The full composition of the product according to Annex III Title 1 is provided in the confidential annex.

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | **Carbon dioxide** |
| **IUPAC or EC name** | **-** |
| **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** |

#### Candidate(s) for substitution

The active substance carbon dioxide contained in the biocidal product is not candidate for substitution in accordance with Article 10 of BPR.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Technical Carbon dioxide | - | Active substance | 124-38-9 | 204-696-9 | 100% |

#### Information on technical equivalence

Not relevant.

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

The product RADAR does not contain any substance of concern as it contains 100% of active substance.

#### Assessment of endocrine disruption (ED) properties of the biocidal product

Not relevant as the product RADAR contains 100% of active substance.

#### Type of formulation

|  |
| --- |
| GA - Gas |

### Hazard and precautionary statements

**Classification and labelling of the products according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Compressed gas  Liquefied gas  Dissolved gas |
| Hazard statement | H280: Contains gas under pressure; may explode if heated |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H280: Contains gas under pressure; may explode if heated |
| Precautionary statements | P251: Pressurized container: Do not pierce or burn, even after use.  P260: Do not breathe gas  P410+P403 : Protect from sunlight. Store in a well-ventilated place. |
|  | |
| Note | **-** |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Professionals – Indoor – House mouse

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Mus musculus* ( House mouse)  Adults and juveniles |
| **Field of use** | Indoor |
| **Application method(s)** |  |
| **Application rate(s) and frequency** | 1-2 canister per unit depending on the device (single or double)  The action time of the product is about 1 minute. |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | 2.8 g gas canister: The carbon dioxide is held in a galvanized steel cylinder with a welded galvanized steel cap which is perced when the trapping device is activated.  8 g gas canister: The carbon dioxide is held in a galvanized steel cylinder with a welded galvanized steel cap which is perced when the trapping device is activated. |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

### General directions for use

#### Instructions for use

|  |
| --- |
| * Do not dilute or add any other substance in the sealed canister. * Regularly check the trapping devices (at least every 8 weeks). * When the trap has been triggered, dispose the dead mouse, clean the trap and replace the canister. |

#### Risk mitigation measures

|  |
| --- |
| * It is recommended that gloves are worn when cleaning the unit and handling rodent bodies |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| - In case of accidental exposure with development of any symptoms, seek medical advice. When asking for medical advice keep packaging or label at hand and call your local poison control center. |

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

|  |
| --- |
| * Dispose of product and its container in accordance with national regulations |

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

|  |
| --- |
| ­ Shelf-life : 2 years  ­ Store and transport the product in accordance with national regulations |

### Other information

|  |
| --- |
| - |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Gas Canister  Sparklet gas Cannister | 2.8 g (105 mm in height and 45 mm in diameter)  8 g sparklet gas canister | Galvanised steel | - | Professional | Yes |

### Documentation

#### Data submitted in relation to product application

**Physico-chemical properties**

Physico-chemical properties studies and analytical methods on the biocidal product RADAR were provided in the competent authority report for the active substance.

**Efficacy data**

The following efficacy study was submitted:

* A laboratory test was carried out with house mice (*Mus musculus*), with exposure to 2,8 g sparklet gas canisters of CO2 in singletrap.
* A laboratory test was carried out with house mice (*Mus musculus*), with exposure to 8 g sparklet gas canisters of CO2 in singleor double chamber traps.

#### Access to documentation

The active substance was initially assessed for listing on the Union list of approved active substances under Directive 98/8/EC, before being included in the annex I of the Biocidal Product regulation.

The applicant is the owner of all the submitted data, and reference to the Competent Authority Report (CAR) on the active substance and the reference product RADAR evaluated in connection with the approval, is made for the assessment of the product RADAR under this application.

## Assessment of the biocidal product

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

Table 2. Intended use # 1 – Trained Professional – Indoor – House mouse

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the authorised use | For the control of mice only (*Mus Musculus*). Indoor use. |
| Target organism (including development stage) | *Mus musculus* (House mouse)  Adults and juveniles |
| Field of use | Indoor |
| Application method(s) | Place the Radar gas canister containing carbon dioxide into the trapping device.  Do not dilute or add any other substance in the sealed cartridge. |
| Application rate(s) and frequency | 2.8 g of carbon dioxide per gas canister, one canister per unit;  8 g of carbon dioxide per sparklet gas canister, one canister per unit |
| Category(ies) of user(s) | Trained Professional |
| Pack sizes and packaging material | Metal gas canister containing 2.8 g carbon dioxide.  Metal Sparklet gas canister containing 8 g carbon dioxide. |

### Physical, chemical and technical properties

Physical, chemical and technical properties of the product RADAR are provided in the CAR of the active substance carbon dioxide (TP 14).

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

The table below summarized Physical, chemical and technical properties (CAR CO2)

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | *-* | - | Mouse trap consisting of a plastic tamper resistant trapping device and a canisterof 100% carbon dioxide gas.  Other: compressed gas (ready-to-use, presented in a gas canister in a tamper resistant trapping device). | Acceptable | CAR, IIIB 3.1 |
| Colour at 20 °C and 101.3 kPa | *-* | - | Gas is colourless at 20ºC, 101.3 kPa | CAR, IIIB 3.1 |
| Odour at 20 °C and 101.3 kPa | *-* | - | Gas is odourless at 20ºC, 101.3 kPa | CAR, IIIB 3.1 |
| Acidity / alkalinity | *-* | - | Radar contains 100% carbon dioxide in a gas canister. Carbon dioxide is a gas under normal conditions of use. It is not technically possible to determine the pH value of a gas.  Notwithstanding the above, it is not necessary to determine the pH value of a solution of carbon dioxide, or the acidity/alkalinity of carbon dioxide (as a gas) on the basis of limited exposure. Under normal conditions of use, the use of carbon dioxide in the product Radar will not cause any elevation in the level of carbon dioxide in air, outside normal atmospheric ranges. | Acceptable | CAR, IIIB 3.5 |
| Relative density / bulk density | - | - | Relative density: 1.527 | Acceptable | CAR, IIIA 3.1.3  A3.1.3/01 Budavari S, O'Neil MJ, Smith A, Heckelman PE and Kinneary JF (1996) Entry for Carbon Dioxide, The Merck Index  A3.1.3/02: Anon (2003) Ideal Gas Law - from Eric Weisstein's World of Physics. http://scienceworld.wolfram.com/physics/IdealGasLaw.html  Deviations from Ideal Gas Law Behavior.  http://chemed.chem.purdue.edu/genchem/topicreview/bp/ch4/deviation5.html  / Published. Applicant's reference number CO2 229  IUCLID |
| Storage stability test – **accelerated storage** | Statement | *-* | Radar contains 100% carbon dioxide in a gas canister. Carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage. This makes it scientifically unnecessary to conduct a 24-month trial on the product, Radar. | Acceptable  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. Nevertheless carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage. . In consequence, FR CA proposed a shelf life of 2 years | CAR, IIIB 3.7  IUCLID |
| Storage stability test – **long term storage at ambient temperature** | Statement | *-* | Radar contains 100% carbon dioxide in a gas canister. Carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage. This makes it scientifically unnecessary to conduct a 24-month trial on the product, Radar. | Acceptable  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. Nevertheless carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage. In consequence, FR CA proposed a shelf life of 2 years | CAR, IIIB 3.7  IUCLID |
| Storage stability test – **low temperature stability test for liquids** | Statement | *-* | Radar contains 100% carbon dioxide in a gas canister. Carbon dioxide is a thermodynamically stable compound which is not expected be affected during low temperature storage. | Acceptable | IUCLID |
| 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 a metal canister. There is no effect from light. | Acceptable | *-* |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Statement | - | The product contains 100% of carbon dioxide compressed in a metal canister. There is no effect from temperature and humidity. | Acceptable | *-* |
| 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 | Acceptable | - |
| Wettability | *-* | *-* | No data provided. | Acceptable  Not relevant as the product is a gas | *-* |
| Suspensibility, spontaneity and dispersion stability | *-* | *-* | No data provided. | Acceptable  Not relevant as the product is a gas | *-* |
| Wet sieve analysis and dry sieve test | *-* | *-* | No data provided. | Acceptable  Not relevant as the product is a gas | *-* |
| Emulsifiability, re-emulsifiability and emulsion stability | *-* | *-* | No data provided. | Acceptable / Not acceptable  Not relevant as the product is a gas | *-* |
| Disintegration time | *-* | *-* | No data provided. | Acceptable  Not relevant as the product is a gas containing 100% of technical substance | *-* |
| Particle size distribution, content of dust/fines, attrition, friability | *-* | *-* | Radar contains 100% carbon dioxide in a ga canister. Carbon dioxide is a gas under the conditions it will be marketed as a biocide. Particle size distribution data is only relevant for products that are supplied as powders or granules, making this data end-point not relevant for Radar. | Acceptable  Not relevant as the product is a gas | CAR IIIB\_3.11 |
| Persistent foaming | *-* | *-* | No data provided. | Acceptable  Not relevant as the product is a gas | *-* |
| Flowability/Pourability/Dustability | *-* | *-* | It is not technically possible to submit data on the technical characteristics of Radar. This is because Radar contains 100% carbon dioxide in a gas canister. The formulation type of Radar (ready-to-use compressed gas) means that there are no characteristics of the product that need to be determined, such as dustability of dusts or flowability of grains, which have not been considered adequately elsewhere. | Acceptable  Not relevant as the product is a gas | CAR IIIB\_3.8 |
| Burning rate — smoke generators | *-* | *-* | No data provided. | Acceptable  Not relevant as product is a ready-to-use compressed gas used in the rapping device (no combustion) | *-* |
| Burning completeness — smoke generators | *-* | *-* | No data provided. | Not relevant as product is a ready-to-use compressed gas used in the trapping device (no combustion) | *-* |
| Composition of smoke — smoke generators | *-* | *-* | No data provided. | Not relevant as product is a ready-to-use compressed gas used in the trapping device (no combustion) | *-* |
| Spraying pattern — aerosols | *-* | *-* | No data provided. | Not relevant as product is a ready-to-use compressed gas used in the bait box | *-* |
| Physical compatibility | Statement |  | Radar contains 100% carbon dioxide in agas canister. Radar is a ready-to-use product so it is not added to any other chemicals during it's normal use. Radar is also not intended for use with any other product. It is for these reasons that it is not necessary to submit data on the physical and chemical compatibility of Radar with other products, chemicals or active ingredients. | Acceptable | CAR IIIB\_3.9 |
| Chemical compatibility |
| Degree of dissolution and dilution stability | *-* | *-* | No data provided. | Acceptable  Not relevant as the product is a gas | *-* |
| Surface tension | *-* | *-* | Surface tension is defined as the force acting on the surface of a liquid, tending to minimise the area of the surface. Radar contains 100 % carbon dioxide in a gas canister. Carbon dioxide is a gas under the conditions it will be marketed as a biocide. It is technically not feasible to determine the surface tension of a gas. There is no approved guideline for testing the surface tension of a gas. It is for these reasons that no surface tension data has been submitted for the biocidal product, Radar. | Acceptable  Not relevant as the product is a gas | CAR IIIB 3.10.1 |
| Viscosity | *-* | *-* | Radar contains 100% carbon dioxide in a gas canister. Carbon dioxide is a gas under the conditions it will be marketed as a biocide. It is technically not feasible to determine the viscosity of a gas. There is no approved guideline for testing the viscosity of a gas. It is for these reasons that no viscosity data has been submitted for the biocidal product, Radar. | Acceptable  Not relevant as the product is a gas | CARIIIB 3.10.2 |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product RADAR is a ready to use compressed gas (GA) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  The appearance of the product is a colourless and odourless gas. Radar 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, FR CA proposed a shelf life of 2 years  Its technical characteristics are acceptable for a gas formulation.  Implication concerning labelling: none |

### Physical hazards and respective characteristics

Physical, chemical and technical properties of the product RADAR are provided in the CAR of the active substance carbon dioxide (PT 14). No further studies are provided in the framework of the dossier.

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

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | statement | - | Radar contains 100% carbon dioxide in a gas canister. Carbon dioxide is thermodynamically stable and therefore does not exhibit explosive properties | Acceptable  Carbon dioxide is thermodynamically stable and therefore does not exhibit explosive properties. Explosive properties test is not necessary | CAR IIIA 3.15 |
| Flammable gases | Statement |  | No data provided. | Acceptable  carbon dioxide is a non-flammable gas that does not support combustion. | Doc A3 PT14 BPD Assessment Report 2007 |
| Flammable aerosols | Statement | *-* | No data provided. | Acceptable  Not relevant as the product RADAR contains 100% of carbon dioxide compressed in a canister, which is not known to be a flammable substance. | - |
| Oxidising gases | Statement | *-* | No data provided. | Examination of the structural formula of carbon dioxide, along with the fact that it is widely accepted that carbon dioxide is thermodynamically stable, suggests that carbon dioxide will not exhibit oxidising properties, even if it could be tested. | Doc A3 PT14 BPD Assessment Report 2007 |
| Gases under pressure | *-* | *-* | The product is a ready-to-use compressed gas, which is classed H280 | Acceptable | Label product RADAR |
| Flammable liquids | Statement | *-* | No data provided. | Acceptable Not relevant as the product is a gas | *-* |
| Flammable solids | Statement | - | No data provided. | Acceptable  Not relevant as the product is a gas | - |
| Self-reactive substances and mixtures | Statement | - | No data provided. | Acceptable  Not applicable as CO2 is a gas | - |
| Pyrophoric liquids | Statement | - | No data provided. | Acceptable  Not relevant as the product is a gas | - |
| Pyrophoric solids | Statement | - | No data provided. | Acceptable  Not relevant as the product is a gas | - |
| Self-heating substances and mixtures | Statement | - | No data provided. | Acceptable  The substance is not known to be a self-heating substance | - |
| Substances and mixtures which in contact with water emit flammable gases | Statement | - | No data provided. | Acceptable  The substance is soluble in water. No emission of flammable gases is expected in water contact | - |
| Oxidising liquids | Statement | *-* | No data provided. | Acceptable  Not relevant as the product is a gas | CAR IIIB 3.3 |
| Oxidising solids | Statement | *-* | No data provided. | Acceptable  Not relevant as the product is a gas | CAR IIIB 3.3 |
| Organic peroxides | Statement | *-* | No data provided. | Acceptable  Not relevant as the product is a gas | - |
| Corrosive to metals | Statement | *-* | Carbon dioxide is not know to corrosive metal. | Acceptable | *-* |
| Auto-ignition temperatures of products (liquids and gases) | Statement | - | No data provided. | Acceptable  carbon dioxide is a non-flammable gas that does not support combustion. | - |
| Relative self-ignition temperature for solids | Statement | - | No data provided. | Acceptable  Not relevant as the product is a gas | - |
| Dust explosion hazard | Statement | - | No data provided. | Acceptable  Not relevant as the product is a gas | - |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties.  Implication concerning labelling:  Contains gas under pressure; may explode if heated – H280 |

### Methods for detection and identification

### *Analytical methods for the active and impurities in the technical material*

Not required in the frame of a simplified national authorisation.

Carbon dioxide is listed in Annex I of regulation (EU) No 528/2012 under Category 6.

***Analytical methods for the active substance in the biocidal product***

Radar contains 100% carbon dioxide in a gas canister.

The analytical method used to detect the concentration of carbon dioxide in Radar is identical to that used for the active ingredient carbon dioxide.

Report: Messer UK Ltd (2004) Validation of Analytical Methods used to Determine the Percentage Concentration of Carbon Dioxide. Applicant’s reference number: CO2 252

Test facilities: No provided

Principle of the method:

Infrared Analysis:

The infrared analyser measures the total carbon dioxide level of the test gas in respect to a zero gas, which is 100% carbon dioxide in this method. The Infrared analyser is “zeroed” using a zero gas of 100% carbon dioxide, and then test gases are analysed.

Detector: SICK MAIHAK UNOR S710 Infrared Analyser.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data of the method provided in the CAR of the active substance IIIA 4.1are reported in the table below:

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | None  The method is specific for carbon dioxide | |
| Linearity | Linearity was studied by carrying out four concentrations (each analysed five times) between 99 -100% carbon dioxide  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |
| Carbon dioxide | 99-100%  Y = Not provided R2 = 0.9912  n=4 |
| Precision/ Accuracy | Accuracy was determined by analysis of 5 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  | | --- | --- | --- | --- | | Fortification level | Mean recovery rate | RSD (%) | n | | 0.118% N2 in CO2 | 100 | 0.01 | 5 | | 0.327 % N2 in CO2 | 99.8 | 0.00 | 5 | | 0.522 % N2 in CO2 | 99.5 | 0.00 | 5 | | 1.01 % N2 in CO2 | 99 | 0.00 | 5 | | |

The analytical method is fully validated for the determination of the active substance carbon dioxide in the product.

Based on the intended uses of the product, no contamination of the environment is foreseen. Analytical methods for carbon dioxide residues in soil, air, water (including drinking water) and sediment are unnecessary. Moreover, the environmental risk assessment shows that CO2, when used as a biocide, does not affect the levels of CO2 found usually in the atmosphere, outside normal range.

As the active substance carbon dioxide is not classified Toxic or Very Toxic, an analytical method for the determination of carbon dioxide residue in human body fluids and tissues is unnecessary.

As the product RADAR is not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of carbon dioxide residue in food/feed of plant and animal origin is unnecessary.

***Analytical methods for the monitoring of residues (soil, water, air, body fluids***

***and tissues and food)***

Not required in the frame of a simplified national authorisation.

Carbon dioxide is listed in Annex I of regulation (EU) No 528/2012 under Category 6.

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The analytical method is fully validated for the determination of the active substance carbon dioxide in the product.  Based on the intended uses of the product, no contamination of the environment is foreseen. Analytical methods for carbon dioxide residues in soil, air, water (including drinking water) and sediment are unnecessary.  Carbon dioxide is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.  The product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of carbon dioxide in food/feed of plant and animal origin is not required. |

### Efficacy against target organisms

#### Function and field of use

RADAR, a ready-to-use compressed gas in a canister containing 100% of carbon dioxide is intended to be used to control mice such as house mouse (Mus musculus). Each canister contains 2.8 g or 8g of carbon dioxide for use in trapping devices.

#### Organisms to be controlled and products, organisms or objects to be protected

RADAR is used to control mice such as house mouse (*Mus musculus domesticus*). This product is intended for use in areas where there is not a severe infestation of rodents. It is not appropriate to use RADAR where there are a lot of rodents, because the unit needs to be re-set every time an animal is caught. The system is intended to monitor rodent activity, and it is therefore unlikely to be tripped regularly.

#### Effects on target organisms, including unacceptable suffering

When mice are exposed to carbon dioxide in RADAR, they are initially knocked out by the narcotic effect of carbon dioxide (when the concentration reaches approximately 30% inside the mouse-trap), and eventually killed (when the carbon dioxide concentration reaches approximately 70%).

#### Mode of action, including time delay

Rats and mice, when exposed to carbon dioxide, are initially knocked out by the narcotic effect of carbon dioxide (when the concentration reaches approximately 30%) and eventually killed (when the carbon dioxide concentration reaches approximately 70%). It is widely reported in the public domain that build-up of carbon dioxide in the blood leads to a condition called ‘respiratory acidosis’. The first symptoms are drowsiness, leading to stupor and coma and ultimately death. This can happen very quickly if the carbon dioxide levels in the blood do not fall.

#### Efficacy data

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Rodenticide | indoor | RADAR product  100% carbon dioxide  (2,8 g CO2 canister in single and dual chamber traps.) | House mice  Mus musculus | Semi-field test  Pen measured 1.7 m2, with a thin layer of sawdust sprinkled on the pen floor. A harbourage (large plastic rat bait box containing wire wool) was provided in the middle of one wall of the pen. A food cube (lab diet in a metal cube) and a water font was placed in the middle of the far wall of the pen. One Radar unit (containing a full aerosol of carbon dioxide) was placed along one of the walls of the pen after the appropriate period of acclimatisation (if any). | Animals were singly caged in the conditions described opposite. One Radar unit was placed in the pen after 0h, 24h or 72h acclimatisation. The test was to continue until the animal was either caught or killed by the Radar unit (for information, note that the longest test period was 7 days). The animals in the pens were observed at hourly intervals during the working day (0900-1700) and at least once during the evening until the mouse was caught or killed.  3 males and 3 females were under test for each acclimatisation period in the pen (0h, 24h, 72h), and there were two replicates of each test (36 animals were tested, in total). | Radar is 100% effective under the test conditions. All mice were caught and subsequently killed by the Radar unit.  Results given in a separate report show that the levels of carbon dioxide reached in the Radar unit within one minute of it being tripped are more than sufficient to kill the mouse reliably and humanely. | B5.10.2/01 to 07 |
| Rodenticide | indoor | RADAR product  100% carbon dioxide  8 g CO2 canister in single and dual chamber traps. | House mice  *Mus musculus* | Semi-field test  Internal method | 2.5m x 3.0m enclosed pen containing 20 wild strain adult Oaklease mice. The mice had been established in this pen for 2 months. Included in the pen were natural harbourages, tunnels, wooden pallets and access to fresh food and water *ad libitum*.  The unit are setup and armed with CO2 cartridge and placed in mouse pen and let until its activation. 1 minute after, the units are opened and the death of the mouse is confirmed. The units are cleaned and the CO2 cartridge inspected. | 100 % of mortality in both unit types | B5.10.2-07  RI = 2 |

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| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) considers that the elements presented in the dossier support the efficacy of the 2,8 and 8 g sparklet gas canister, for use in trapping devices indoors against the house mouse (*Mus musculus*) by professional users. |

#### Occurrence of resistance and resistance management

Resistance of pests to pesticides is defined as the ability of a given population to withstand a poison that was effectively lethal to earlier generations of the species. Resistance to carbon dioxide will not develop because, when used as a biocide, it will be lethal to the target rodent in a single dose (as demonstrated by the information submitted for the representative product containing carbon dioxide, Radar). This means that there is no mechanism for resistance to carbon dioxide to develop because target organisms are never exposed to sub-lethal concentrations of carbon dioxide (as a biocide), unlike the multi-feed pesticides such as anticoagulant rodenticides.

#### Known limitations

The RADAR unit must not be subjected to extremes of temperature or come into contact with large volumes of water because this may affect the electronic circuitry in the unit.

RADAR is not recommended for use with other biocidal products.

#### Evaluation of the label claims

RADAR is used to control mice such as house mouse (*Mus musculus domesticus*). This product is intended for use in areas where there is not a severe infestation of rodents. It is not appropriate to use RADAR where there are a lot of rodents, because the unit needs to be re-set every time an animal is caught. The system is intended to monitor rodent activity, and it is therefore unlikely to be tripped regularly.

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

#### The RADAR product is not intended to be used with another biocidal product.

### Considerations for human health

The product RADAR has been considered in relation to the simplified authorisation procedure (under Reg. (EU) 528/2012, chapter V, article 25).

An assessment of potential SOCs (Substances of Concern) is not relevant, as the product RADAR contains no co-formulants. Thus RADAR contains carbon dioxide and no substances of concern. FR CA therefore considers that the biocidal product RADAR does not meet the classification criteria for skin corrosion and irritation, eye irritation, respiratory tract irritation, skin sensitization, respiratory sensitization (ADS), or acute toxicity.

The product is not classified for human health effects.

On this basis, the RADAR product meets conditions of art. 25 from the human health perspective.

### Considerations for animal health

There are no substances of concern present and the product is not classified, therefore the

FR CA considers that there is no concern for animal health.

### Considerations for the environment

The product RADAR has been considered in relation to the simplified authorisation procedure (under Reg. (EU) 528/2012, chapter V, article 25).

An assessment of potential SOCs (Substances of Concern) is not relevant as the product RADAR contains no co-formulants. Thus RADAR contains carbon dioxide and no substances of concern. FR CA therefore considers that the biocidal product RADAR does not meet the classification as hazardous to the environment under Reg. (EC) 1272/2008.

The product is not classified for the environment.

On this basis, the RADAR product meets conditions of art. 25 from an environmental perspective.

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

To avoid risks to man, animals and the environment, comply with the instructions for use.

### Assessment of a combination of biocidal products

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