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 MINOR CHANGE OF NATIONAL AUTHORISATION APPLICATIONS**



FANGA RONGEUR PRO 25

Product type 14

[Brodifacoum included in the Union list of approved active substances]

Case Number in R4BP: [BC-QX033191-16]

Evaluating Competent Authority: [France]

Date : 13/04/2018

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**History of the dossier** (**updated PAR – 2017)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | FR |  | 30/09/2014 | Initial assessment  FANGA RAT-DICAL TECH |
| NA-MAC  And post-authorisation requirement | FR | BC-WG017333-42 | 18/05/2016 | Amendement of the authorisation : addition of   * general public use * outdoor uses * tagrget organisms ; * trade name; * manufacturers of the product * packaging for professional (loose)   Post-authorisation: change of shelf-life and efficacy data. |
| NA-ADC | FR | BC-EQ250069-31 | 19/12/2016 | Addition of others trades names and manufacturers of the product |
| NA-BBS | FR | BC-CD026029-62 | 05/07/2017 | Same product FANGA RONGEUR PRO 25 |
| NA-MIC | FR | BC-QX033191-16 | 13/04/2018 | Change of the support  Addition of the packaging for the professional and non professional |

**Uses authorised (0.0025% of brodifacoum)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Users** | **Target organisms** | **Application rate** | **Field of use** | **Packagings** |
| Professionals | Rat *(Rattus norvegicus and rattus ratts)* | 200 g / bait point separated by 5-10 meters | In and around buildings  Open areas  Waste dumps and landfills | Individual sachets  (PE )  And loose  Minimum pack size: 5 kg |
| Mice (*Mus musculus*) | 40 g of product / bait station at separated to 1-2 meters |
| Non professionnals | Rat (*R*attus *norvegicus and rattus rattus*) | 200g / bait point separated by 5-10 meters | In and around buildings  Open areas | Individual sachets  /PE:  Maximum pack size: 1.5 kg |
| Mice (*Mus musculus*) | 40 g / bait point separated by 1-2 meters |

# General information about the product application

* **Minor change 2017**

The minor change on FANGA RONGEUR PRO 25 consists in a modification of the support from corn to wheat and the addition of primary and secondary packages.

In the following, sections that are subject to changes due to the minor change are indicated only. For all other sections of the PAR, please refer to the product assessment report related to FANGA RAT-DICAL TECH product authorisation under Regulation UE n° 528/2012.

## Documentation

### Data submitted in relation to product application

* **Minor change 2017**

**Efficacy data**

The following efficacy studies were submitted:

* A free-choice laboratory test was carried out with rats (*Rattus norvegicus* wild strain), with exposure to 15 month aged **FANGA B+ RONGEUR** (0.001 % brodifacoum) for 4 days.
* A free-choice laboratory test was carried out with rats (*Rattus rattus* wild strain), with exposure to 3 years aged **FANGA B+ RONGEUR** (0.001 % brodifacoum) for 4 days.
* A field test was carried out with mice (*Mus musculus*), with exposure to 2 years aged **FANGA B+ RONGEUR** (0.001 % brodifacoum).
* A field test was carried out with rats (*Rattus norvegicus*), with exposure to 3 years aged **FANGA B+ RONGEUR** (0.001 % brodifacoum).
* A field test was carried out with rats (*Rattus rattus*), with exposure to 15 months aged **FANGA B+ RONGEUR** (0.001 % brodifacoum).

# Summary of the product assessment

## Classification, labelling and packaging

### Harmonised classification of the active substance

* **Minor change 2017**

|  |  |  |
| --- | --- | --- |
| **Classification - Regulation (EC) 1272/2008** | | |
| Hazard category | Acute Tox. 1 | |
| Repr. 1A | |
| STOT RE 1 | |
| Aquatic Acute 1 | |
| Aquatic Chronic 1 | |
| Hazard statements | H310 | Fatal in contact with skin. |
| H300 | Fatal if swallowed. |
| H330 | Fatal if inhaled |
| H372 | Causes damage to organs through prolonged or repeated exposure. |
| H360D | May damage the unborn child |
| H400 | Very toxic to aquatic life- M-factor = 10 |
| H410 | Very toxic to aquatic life with long lasting effects M-factor = 10 |
| Specific Concentration Limits | Repr. 1A; H360D: C ≥ 0,003 %  STOT RE 1; H372: C ≥ 0,02 %  STOT RE 2; H373: 0,002 % ≤ C < 0,02 % | |

### Packaging of the biocidal product

* **Minor change 2017**

For professionals

FANGA RONGEUR PRO 25 is supplied in:

* Rats: 10-20-25-30-40-45-50-60-90-100-200 g PE or PP sachet
* Mice 10-20-30-40 PE or PP sachet

Sachets are packed in:

* Paper bags, several layers with one or without plastic film in PE (5-10-15-20-25-30 kg)
* PE/PP bucket (5-10-15-18-20-25-30 kg)
* Cardboard box (5-10-12-15-20-25-30-50kg)
* Metal box without lacquer (0.1-0.2-0.3-0.4-0.5-0.6-0.7-0.8-0.9-1-1.1-1.2-1.3-1.4-1.5kg)
* Bait box in plastic PET/PP/PE/PVC (up to 1.5 kg)

FANGA RONGEUR PRO 25 is also supplies in loose:

* Paper bags, several layers with one plastic film in PE (5-10-15-20-25-30 kg)
* PE or PP sachet (50-100-150-200-250-300-350-400-450-500-550-600-650-700-750-800-850-900-950-1000-1050-1100-1150-1200-1250-1300-1350-1400-1450-1500 g)
* PE/PP bucket (5-10-15-18-20-25-30 kg)
* Cardboard box with one plastic bag inside (5-10-12-15-20-25-30-50 kg)
* Metal box without lacquer (0.1; 0.2; 0.3; 0.4; 0.5; 0.6; 0.7; 0.8; 0.9; 1; 1.1; 1.2; 1.3; 1.4; 1.5 kg)
* Bait box in plastic PET/PP/PE/PVC (up to 1.5 kg)

For non-professionals

FANGA RONGEUR PRO 25 is supplied in:

* Rats: 10-20-25-30-40-45-50-60-90-100-200 g PE or PP sachets
* Mice: 10-20-30-40 PE or PP sachet

Sachets are packed in:

* PE/PP sachet (50-100-150-200-250-300-350-400-450-500-550-600-650-700-750-800-850-900-950-1000-1050-1100-1150-1200-1250-1300-1350-1400-1450-1500 g)
* PE/PP bucket (0.1; 0.2; 0.3; 0.4; 0.5; 0.6; 0.7; 0.8; 0.9; 1.0; 1.1; 1.2; 1.3; 1.4; 1.5 kg)
* Cardboard box (0.1; 0.2; 0.3; 0.4; 0.5; 0.6; 0.7; 0.8; 0.9; 1.0; 1.1; 1.2; 1.3; 1.4; 1.5 kg)
* Metal box without lacquer (0.1; 0.2; 0.3; 0.4; 0.5; 0.6; 0.7; 0.8; 0.9; 1.0; 1.1; 1.2; 1.3; 1.4; 1.5 kg)
* Bait box in plastic PET/PP/PE/PVC (up to 1.5kg)
* PEHD flacon (0.1; 0.2; 0.3; 0.4; 0.5; 0.6; 0.7; 0.8; 0.9; 1.0; 1.1; 1.2; 1.3; 1.4; 1.5 kg)

## Physico/chemical properties and analytical methods

### Biocidal product

#### 2.3.2.2 Physico-chemical properties

* **Minor change 2017**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| Storage stability test – **accelerated storage** | No new data were provided by the applicant to support this minor change dossier. A read across with product FANGA B+ RONGEUR and FANGA RONGEUR PRO is proposed by the applicant. These two products contain respectively 0.001% w/w and 0.005% w/w of brodifacoum and for both of them the nature of grain is wheat. A read across with these two biocides products is then acceptable. Based on the shelf life of those products (one year), a shelf life of one year can be granted for the biocidal FANGA RONGEUR PRO 25. | | | |
| Storage stability test – **long term storage at ambient temperature** |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product FANGA RONGEUR PRO 25 is a ready to use bait formulation. According to the read across with both product FANGA RONGEUR PRO and FANGA B+ RONGEUR, all studies have been performed in accordance with the current requirements.  The appearance of the product is blue wheat grains.  According to the storage stability a shelf life of one year at ambient temperature can be grant for the biocidal product.  According to the read across with both product FANGA RONGEUR PRO and FANGA B+ RONGEUR, a shelf life of one year can be granted for the biocidal FANGA RONGEUR PRO 25.  eCA recommends to store away from light due to the sensitivity of the active substance to light.  Its technical characteristics are acceptable an RB ready to use formulation. |

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| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| Based on the differences, the physico-chemical hazards of the product FANGA RONGEUR PRO 25 are similar between the old and new composition.  Therefore refer to the product assessment report related to FANGA RAT-DICAL TECH product authorisation under Regulation UE n° 528/2012 for the physico-chemical hazards of the product. |

### Analytical methods for detection and identification

#### Analytical methods for determining relevant components and/or residues in different matrices

* **Minor change 2017**

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| Provided analytical methods on the product FANGA RONGEUR PRO and FANGA B+ RONGEUR are fully validated for the determination of the active substance bromadiolone at 10 ppm and at 50 ppm.  For the analytical methods for determining relevant components and/or residues in different matrices, please refer to the product assessment report related to FANGA RONGEUR PRO and FANGA B+ RONGEUR product authorisation under Regulation UE n° 528/2012. |

## 2.5 Effectiveness against target organisms

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

* **Minor change 2017**

To support the efficacy of the new formulation of the product FANGA RONGEUR PRO 25 where the difference between the new and the old composition consists on a change in cereal support (wheat instead corn), the applicant has submitted studies with the product FANGA B+ RONGEUR.

### Effect on target organisms and efficacy

* **Minor change 2017**

French competent authorities (FR CA) considers that the elements presented in the dossier confirm, when the support of the formulation is changed from corn to wheat, the efficacy of the product FANGA RONGEUR PRO 25 against house mice (Mus musculus), black rats (Rattus rattus) and brown rats (Rattus norvegicus) for use in and around buildings, open areas by professional and non-professional users, and only by professional users in waste dumps and landfills.

Uses and doses validated for FANGA RONGEUR PRO 25 are the following:

|  |  |  |  |
| --- | --- | --- | --- |
| **Product** | **Target organisms** | **Application rate and intervals** | **Use area** |
| FANGA RONGEUR PRO 25  Bait containing 0.0025% w/w of brodifacoum. | Rats (*Rattus norvegicus* and *Rattus rattus*) | 200 g / bait point separated by 5 - 10 meters | In and around building, open areas, waste dumps and landfills |
| Mice (*Mus musculus*) | 40 g / bait point separated by 1 - 2 meters | In and around building, open areas, waste dumps and landfills |

### Evaluation of the label claim

* **Minor change 2017**

French competent authorities (FR CA) assessed that the product FANGA RONGEUR PRO 25 has shown a sufficient efficacy for the control of mice (*Mus musculus*) and rats (*Rattus norvegicus and Rattus norvegicus*) in and around buildings, in open areas by professional and non professional users and, in waste dumps and landfills by professional users only.

The application rates validated are the following:

House mice (Mus musculus): 40 g baiting point separated by 1-2 m.

Rats (Rattus norvegicus and Rattus rattus): 200 g baiting point separated by 5-10 m

## Description of the intended use

### Risk assessment for human health

* **Minor change 2017**

The minor change on FANGA RONGEUR PRO 25 consists in a modification of the support from corn to wheat and the addition of primary and secondary packages.

No impact on the conclusions is expected.

Please refer to the product assessment report related to FANGA RAT-DICAL TECH product authorisation under Regulation UE n° 528/2012.

# Proposal for decision – Minor Change 2017

1. **Administrative information**

**1.1. Trade name(s) of the product**

| **Trade name(s)[[1]](#footnote-1)** | *FANGA RONGEUR PRO 25* |
| --- | --- |
|  |  |

**1.2. Authorisation holder**

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | TRIPLAN SA |
| **Address** | BP 258 L Poste française  AD500 Andorra La Vella  ANDORRE |
| **Authorisation number** |  | |

**1.3. Manufacturer(s) of the product**

|  |  |
| --- | --- |
| **Name of manufacturer** | SOFAR FRANCE |
| **Address of manufacturer** | SOFAR FRANCE  BP 2  29190 PLEYBEN  France |
| **Location of manufacturing sites** | SOFAR FRANCE  BP 2  29190 PLEYBEN  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | *IRIS* |
| **Address of manufacturer** | *1126A, Avenue du Moulinas, Route de Saint Privat*  *30340*  *SALINDRES*  *France* |
| **Location of manufacturing sites** | *1126A, Avenue du Moulinas, Route de Saint Privat*  *30340*  *SALINDRES*  *France* |

|  |  |
| --- | --- |
| **Name of manufacturer** | *NOXIMA* |
| **Address of manufacturer** | *Carrefour Jean Monnet - Lacroix St-Ouen*  *60201*  *COMPIEGNE*  *France* |
| **Location of manufacturing sites** | *Carrefour Jean Monnet - Lacroix St-Ouen*  *60201*  *COMPIEGNE*  *France* |

|  |  |
| --- | --- |
| **Name of manufacturer** | *INDUSTRIAL CHIMICA SRL* |
| **Address of manufacturer** | *Via Sorgaglia 40*  *35020*  *ARRE (PD)*  *Italy* |
| **Location of manufacturing sites** | *Via Sorgaglia 40*  *35020*  *ARRE (PD)*  *Italy* |

|  |  |
| --- | --- |
| **Name of manufacturer** | HDA – HYGIENE ET DERATISATION D‘AUVERGNE |
| **Address of manufacturer** | ZA LA CHARME MENETROL  63200  RIOM  France |
| **Location of manufacturing sites** | ZA LA CHARME MENETROL  63200  RIOM  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | SAS RATOUCY |
| **Address of manufacturer** | SAS RATOUCY  29 rue de la foret – LOOZE - Bp 145  89303 Joigny Cedex  France |
| **Location of manufacturing sites** | SAS RATOUCY  29 rue de la foret – LOOZE - Bp 145  89303 Joigny Cedex  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | SARL LFT SETA |
| **Address of manufacturer** | SARL LFT SETA  Château de Puèchassaut  81440 BROUSSE LAUTREC  France |
| **Location of manufacturing sites** | SARL LFT SETA  Château de Puèchassaut  81440 BROUSSE LAUTREC  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | *FARMAVIT OOD* |
| **Address of manufacturer** | *Bul Tsar Boris III, n°62, Office 1*  *1612 SOFIA*  *Bulgaria* |
| **Location of manufacturing sites** | *Industrialna 2 str, Pleven District*  *5960*  *GULIANTSI*  *Bulgaria* |

|  |  |
| --- | --- |
| **Name of manufacturer** | *TAKAMAKA INDUSTRIES* |
| **Address of manufacturer** | *Ilot- Batiment 8 - PAE LA MARE*  *97438 SAINTE-MARIE*  *France* |
| **Location of manufacturing sites** | *Ilot- Batiment 8 - PAE LA MARE*  *97438 SAINTE-MARIE*  *France* |

**1.4. Manufacturer(s) of the active substance(s)**

|  |  |
| --- | --- |
| **Active substance** | 11 - Brodifacoum |
| **Name of manufacturer** | ACTIVA/TEZZA |
| **Address of manufacturer** | VIA FELTRE 32  20132  MILANO  Italy |
| **Location of manufacturing sites** | PM TEZZA SRL  VIA TRE PONTI 22  37050  S. MARIA DI ZEVIO (VR)  Italy |

* **2. Product composition and formulation**

**2.1. Qualitative and quantitative information on the composition of the biocidal product**

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Brodifacoum  (pure) | 3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-napthyl]-4-hydroxycoumarin | Active substance | 56073-10-0 | 259-980-5 | 0.0025 |

**2.2. Type of formulation**

|  |
| --- |
| RB-(bait ready for use): grain |

* **3. Hazard and precautionary statements[[2]](#footnote-2)**

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** | |
| Hazard category | STOT RE 2 |
| Hazard statements | H373: May cause damage to organs (blood) through prolonged or repeated exposure |
| **Labelling -** | |
| Signal words: | Danger |
| Hazard statements: | H373: May cause damage to organs (blood) through prolonged or repeated exposure |
| Precautionnary statements | P260: Do not breathe dust/fumes/gas/mist/vapours/spray  P314: Get medical advice/attention if you feel unwell  P501: Dispose of contents/container to … [… in accordance with local/regional/national/international regulation (to be specified)]. |

* **4. Authorised use(s)**

**4.1. Use description**

**Table 1. Use # 1 – House mice and/or rats – trained professionals – indoor**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | Mus musculus (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Bait formulations:  - Ready-to-use bait to be used in tamper-resistant bait stations[[3]](#footnote-3)  - *[Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  - Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g grains/secured bait point separated by 5-10 m.  - House mice (*Mus musculus*): 40 g grains/secured bait separated by 1 - 2 m |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only*** *: minimum pack size of 5 kg)*  - Bait formulations:  FANGA RONGEUR PRO 25 is supplied in:   * Rats: 10-20-25-30-40-45-50-60-90-100-200 g PE or PP sachet * Mice 10-20-30-40 PE or PP sachet   Sachets are packed in:   * Paper bags, several layers with one or without plastic film in PE (5; 10; 15; 20; 25; 30 kg) * PE/PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 12; 15; 20; 25; 30; 50 kg) * Bait box in plastic PET/PP/PE/PVC (40; 200 g)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE (5;10; 15; 20; 25; 30 kg) * PE or PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 15; 18; 20; 25; 30 kg) * Bait box in plastic PET/PP/PE/PVC (40; 200 g) |

***4.1.1.* *Use-specific instructions for use***

|  |
| --- |
| - Remove the remaining product at the end of treatment period.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice. |

***4.1.2 Use-specific risk mitigation measures***

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| - Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.  - Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  - To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.  *-* Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.  - Do not use the product in pulsed baiting treatments. |

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

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| --- |
| - When placing bait points close to water drainage systems, ensure that bait contact with water is avoided. |

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

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

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**4.2. Use description**

**Table 2. Use # 2 Mice and/or rats – trained professionals – outdoor around buildings**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor around buildings |
| **Application method(s)** | Bait formulations:  - Ready-to-use bait to be used in tamper-resistant bait stations.  - *[Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  - Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g grains/secured bait point separated by 5-10 m.  - House mice (*Mus musculus*): 40 g grains/secured bait separated by 1 - 2 m |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only*** *: minimum pack size of 5 kg)*  - Bait formulations:  FANGA RONGEUR PRO 25 is supplied in:   * Rats: 10-20-25-30-40-45-50-60-90-100-200 g PE or PP sachet * Mice 10-20-30-40 PE or PP sachet   Sachets are packed in:   * Paper bags, several layers with one or without plastic film in PE (5; 10; 15; 20; 25; 30 kg) * PE/PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 12; 15; 20; 25; 30; 50 kg) * Bait box in plastic PET/PP/PE/PVC (40; 200 g)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE (5;10; 15; 20; 25; 30 kg) * PE or PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 15; 18; 20; 25; 30 kg) * Bait box in plastic PET/PP/PE/PVC (40; 200 g) |

***4.2.1.* *Use-specific instructions for use***

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| - Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.  - Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.  - Remove the remaining product at the end of treatment period.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice.  *- [For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species].* |

***4.2.2 Use-specific risk mitigation measures***

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| --- |
| - Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.  - Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  - To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice*.*  - Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.  - Do not use this product in pulsed baiting treatments.  - Do not apply this product directly in the burrows. |

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

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| --- |
| - When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided. |

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

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

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**4.3. Use description**

**Table 3. Use # 3 – Rats – trained professionals – Outdoor open areas & waste dumps**

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| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor open areas  Outdoor waste dumps |
| **Application method(s)** | - Ready-to-use bait to be used in tamper-resistant bait stations.  *- [Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  - Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g grains/secured bait point separated by 5-10 m. |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only*** *: minimum pack size of 5 kg)*  - Bait formulations:  FANGA RONGEUR PRO 25 is supplied in:   * Rats: 10-20-25-30-40-45-50-60-90-100-200 g PE or PP sachet   Sachets are packed in:   * Paper bags, several layers with one or without plastic film in PE (5; 10; 15; 20; 25; 30 kg) * PE/PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 12; 15; 20; 25; 30; 50 kg) * Bait box in plastic PET/PP/PE/PVC (200 g)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE (5;10; 15; 20; 25; 30 kg) * PE or PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 15; 18; 20; 25; 30 kg) * Bait box in plastic PET/PP/PE/PVC (200 g) |

***4.3.1.* *Use-specific instructions for use***

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| - Protect bait from the atmospheric conditions. Place the bait stations in areas not liable to flooding.  - Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.  - Remove the remaining product at the end of treatment period *[Not applicable where explicitly authorised according to addenda 4]*.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice.  *- [For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species].* |

***4.3.2 Use-specific risk mitigation measures***

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| - Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.  - To reduce risk of secondary poisoning, search for and remove dead rodents during treatmentat frequent intervals*,* in line with the recommendations provided by the relevant code of best practice.  - Do not apply this product directly in the burrows. |

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

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| - When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided. |

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

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

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**4.4. Use description**

**Table 4. Use # 4 *(not relevant in France)* – House mice – professionals – indoor**

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| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations[[4]](#footnote-4) |
| **Application rate(s) and frequency** | Bait products:  - House mice (*Mus musculus*): 40 g grains/secured bait separated by 1 - 2 m |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only*** *: minimum pack size of 5 kg)*  - Bait formulations:  FANGA RONGEUR PRO 25 is supplied in:   * Mice 10-20-30-40 PE or PP sachet   Sachets are packed in:   * Paper bags, several layers with one or without plastic film in PE (5; 10; 15; 20; 25; 30 kg) * PE/PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 12; 15; 20; 25; 30; 50 kg) * Bait box in plastic PET/PP/PE/PVC (40g)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE (5;10; 15; 20; 25; 30 kg) * PE or PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 15; 18; 20; 25; 30 kg) * Bait box in plastic PET/PP/PE/PVC (40g) |

***4.4.1.* *Use-specific instructions for use***

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| - The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice. |

***4.4.2 Use-specific risk mitigation measures***

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

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| - When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided. |

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

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

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**4.5. Use description**

**Table 5. Use # 5 *(not relevant in France)* – Rats – professionals – indoor**

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| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | Bait products:  - Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g grains/secured bait point separated by 5-10 m. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only*** *: minimum pack size of 5 kg)*  - Bait formulations:  FANGA RONGEUR PRO 25 is supplied in:   * Rats: 10-20-25-30-40-45-50-60-90-100-200 g PE or PP sachet   Sachets are packed in:   * Paper bags, several layers with one or without plastic film in PE (5; 10; 15; 20; 25; 30 kg) * PE/PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 12; 15; 20; 25; 30; 50 kg) * Bait box in plastic PET/PP/PE/PVC (200 g)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE (5;10; 15; 20; 25; 30 kg) * PE or PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 15; 18; 20; 25; 30 kg) * Bait box in plastic PET/PP/PE/PVC (200 g) |

***4.5.1.* *Use-specific instructions for use***

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| - The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice. |

***4.5.2 Use-specific risk mitigation measures***

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

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| - When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided. |

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

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

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**4.6. Use description**

**Table 6. Use # 6 *(not relevant in France)* – House mice and/or rats – professionals – outdoor around buildings**

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| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | Mus musculus (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor around buildings |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | Bait products:  - Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g grains/secured bait point separated by 5-10 m.  - House mice (*Mus musculus*): 40 g grains/secured bait separated by 1 - 2 m |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only*** *: minimum pack size of 5 kg)*  - Bait formulations:  FANGA RONGEUR PRO 25 is supplied in:   * Rats: 10-20-25-30-40-45-50-60-90-100-200 g PE or PP sachet * Mice 10-20-30-40 PE or PP sachet   Sachets are packed in:   * Paper bags, several layers with one or without plastic film in PE (5; 10; 15; 20; 25; 30 kg) * PE/PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 12; 15; 20; 25; 30; 50 kg) * Bait box in plastic PET/PP/PE/PVC (40; 200 g)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE (5;10; 15; 20; 25; 30 kg) * PE or PP bucket (5; 10; 15; 18; 20; 25; 30 kg) * Cardboard box (5; 10; 15; 18; 20; 25; 30 kg) * Bait box in plastic PET/PP/PE/PVC (40; 200 g) |

***4.6.1.* *Use-specific instructions for use***

|  |
| --- |
| - Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.  - The bait stations should be visited *[for mice -* at least every 2 to 3 days at*]* *[for rats -* only 5 to 7 days after*]* the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.  - Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice. |

***4.6.2 Use-specific risk mitigation measures***

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| - Do not apply this product directly in the burrows. |

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

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| - When placing bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided. |

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

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

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**4.7. Use description**

**Table 7. Use # 7 – House mice – general public – indoor**

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| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait *[in sachets for loose bait]* to be used in tamper-resistant bait stations[[5]](#footnote-5). |
| **Application rate(s) and frequency** | Bait products:  - House mice (*Mus musculus*): 40 g grains/secured bait separated by 1 - 2 m |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | FANGA RONGEUR PRO 25 is supplied in:   * Mice: 10-20-30-40 PE or PP sachet   Sachets are packed in:   * PE/PP sachet (up to 150 g) * PE/PP bucket (up to 150g) * Cardboard box (up to 150g) * Metal box without lacquer (up to 150g) * Bait box in plastic PET/PP/PE/PVC (40g) * PEHD flacon (up to 150g) |

***4.7.1.* *Use-specific instructions for use***

|  |
| --- |
| - The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. |

***4.7.2 Use-specific risk mitigation measures***

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

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

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

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**4.8. Use description**

**Table 8. Use # 8 – Rats – general public – indoor**

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| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Indoor. |
| **Application method(s)** | Ready-to-use bait *[in sachets for loose bait]* to be used in tamper-resistant bait stations2. |
| **Application rate(s) and frequency** | Bait products:  - Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g grains/secured bait point separated by 5-10 m. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | FANGA RONGEUR PRO 25 is supplied in:   * Rats: 10-20-25-30-40-45-50-60-90-100-150 g PE or PP sachets   Sachets are packed in:   * PE/PP sachet (up to 150 g) * PE/PP bucket (up to 150g) * Cardboard box (up to 150g) * Metal box without lacquer (up to 150g) * PEHD flacon (up to 150g) |

***4.8.1.* *Use-specific instructions for use***

|  |
| --- |
| - The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. |

***4.8.2 Use-specific risk mitigation measures***

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

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

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

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**4.9. Use description**

**Table 9. Use # 9 – Rats – general public – outdoor around buildings**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor around buildings |
| **Application method(s)** | Ready-to-use bait *[in sachets for loose bait]* to be used in tamper-resistant bait stations2. |
| **Application rate(s) and frequency** | Bait products:  - Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g grains/secured bait point separated by 5-10 m. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | FANGA RONGEUR PRO 25 is supplied in:   * Rats: 10-20-25-30-40-45-50-60-90-100-150 g PE or PP sachets   Sachets are packed in:   * PE/PP sachet (up to 150 g) * PE/PP bucket (up to 150g) * Cardboard box (up to 150g) * Metal box without lacquer (up to 150g) * PEHD flacon (up to 150g) |

***4.9.1.* *Use-specific instructions for use***

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| - Place the bait stations in areas not liable to flooding.  - Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.  - The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. |

***4.9.2 Use-specific risk mitigation measures***

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

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

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

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**5. General directions for use**

**5.1. Instructions for use**

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| **FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS**  - Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.  - Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.  - Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.  - The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.  - The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).  - Where possible, bait stations must be fixed to the ground or other structures.  - Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened *(see section 5.3 for the information to be shown on the label)*.  - *[If national policy or legislation requires it]* When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.  - Bait should be secured so that it cannot be dragged away from the bait station.  - Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.  - Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.  - *[Where required by the risk assessment:*  - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.  ***FOR TRAINED PROFESSIONAL ONLY****- The* frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.  - If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.  - If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.  ***FOR PROFESSIONNALS ONLY*** Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  ***FOR PROFESSIONNALS ONLY*** Remove the remaining bait or the bait stations at the end of the treatment period.  *- Instructions for use that are "bait-specific":*   * *Bait in sachets: [For non-emptiable sachets - Do not open the sachets containing the bait]*. * *Loose pellets-granules, grains: Place the bait in the baiting point by using a dosage devise. Specify the methods to minimise dust (e.g. wet wiping).*   **FOR NON PROFESSIONAL USERS**  - Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.  - Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.  - Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.  - Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).  - Where possible, bait stations must be fixed to the ground or other structures.  - *[*Do not open the sachets containing the bait *- where relevant for the bait formulation in the product].*  - Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.  - Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.  - Do not place bait stations near water drainage systems where they can come into contact with water.  - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.  - Remove the remaining bait or the bait stations at the end of the treatment period. |

**5.2. Risk mitigation measures**

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| **FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS**  - Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*".  - The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only".  - ***FOR TRAINED PROFESSIONAL ONLY*** Do not use in areas where resistance to the active substance can be suspected.  - Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.  - ***FOR TRAINED PROFESSIONAL ONLY*** Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.  - Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.  - Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.  - ***FOR PROFESSIONAL ONLY*** To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). *[Where relevant, specify if more frequent or daily inspection is required].*  - ***FOR PROFESSIONAL ONLY*** Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.  - ***FOR PROFESSIONAL ONLY.*** The product information (i.e. label and/or leaflet) shall clearly show that:   * the product shall not be supplied to the general public (e.g. "for professionals only"). * the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only"). * users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").   - ***FOR PROFESSIONAL ONLY*** Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.  **FOR NON PROFESSIONAL USERS**  - Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  - Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).  - The product information (i.e. label and/or leaflet) shall clearly show that:  the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").  users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").  - Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.  - Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.  - Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*. |

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

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| - This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.  - Antidote: Vitamin K1 administered by medical/veterinary personnel only.  - In case of:  - Dermal exposure, wash skin with water and then with water and soap.  - Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.  - Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label *[insert* country specific information*]*. Contact a veterinary surgeon in case of ingestion by a pet *[insert* country specific information*]*  - Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre *[insert national phone number]*"  - Hazardous to wildlife. |

**5.4. Instructions for safe disposal of the product and its packaging**

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| - At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*. |

**5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

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| - Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.  - Store in places prevented from the access of children, birds, pets and farm animals.  - Shelf life: 1 year. |

**6. Other information**

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| - (**in France only** The data required in post-authorization of decision n° FR-2014-0171 (30 th September 2014) related to the monitoring of the resistance phenomenon of rodent populations toward the active substance brodifacoum are maintained. Results of the resistance monitoring must be submitted at the renewal of the product.)  - Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.  - Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.  - This product contains a bittering agent and a dye. |

# Appendices

Annex 1: Summary of product characteristics

*See separated file.*

Annex 2: List of studies reviewed

##### List of new data[[6]](#footnote-6) submitted in support of the evaluation of the active substance

##### List of new data submitted in support of the evaluation of the biocidal product

| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | | **Data protection claimed** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Yes** | **No** | **Yes** | **No** |
| B3 | B3.1, B3.5, B3.7, B3.8 | Forand V | 2012 | Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54±2°C on FANGA RAT-DICAL TECH in compliance with CIPAC MT 46.3 (CIPAC Handbook J – 2000). DEFITRACES, report n°11-920010-029 of 15 February 2012, GLP, unpublished. | TRIPLAN |  |  |  |  |
| B3 | B3.2/3, B3.4, B3.6, B3.8 | Colombies N | 2012 | Physico chemical tests on FANGA RAT-DICAL TECH. DEFITRACES, report n° 11-920010-028 of 22 February 2012, GLP, unpublished. | TRIPLAN |  |  |  |  |
| B3 | B3.7, B3.8, B3.12 | Grevin P | 2012 | Physico chemical tests before and after an accelerated storage procedure for 14 days at 54 ± 2°C on FANGA RAT-DICAL TECH. DEFITRACES, Report 12-920010-011 of 27 September 2012, GLP, unpublished | TRIPLAN |  |  |  |  |
| B4 | B4.1.1 | Ricau H | 2012 | Analytical method validation for the determination of brodifacoum in the FANGA BLOC SP PRO in compliance with SANCO/3030/99 rev.4 from 11/07/00. DEFITRACES, Report n° 11-920010-015 of 23 January 2012, GLP, unpublished. | TRIPLAN |  |  |  |  |
| B4 | B4.1.1 | Ricau H | 2012 | Analytical method validation for the determination of brodifacoum in the FANGA BLOC SP PRO in compliance with SANCO/3030/99 rev.4 from 11/07/00. DEFITRACES, amended report n° 11-920010-015 of 04 May 2012, GLP, unpublished. | TRIPLAN |  |  |  |  |
| B4 | B4.1.2 | Ricau H | 2012 | Analytical method validation for the determination of brodifacoum in the FANGA RAT-DICAL TECH in compliance with SANCO/3030/99 rev.4 from 11/07/00. DEFITRACES, Report n° 11-920010-031 of 28 February 2012, GLP, unpublished. | TRIPLAN |  |  |  |  |
| B5 | B5.10.2 | XXX | XXX | Palatability of « FANGA RAT-DICAL TECH » (25 ppm brodifacoum) ready-to-use bait targeting brown rat (*Rattus norvegicus*) and house mouse (*Mus musculus*). XXX, unpublished. | TRIPLAN |  |  |  |  |
| B5 | B5.10.2/01 | XXX | XXX | Study on the palatability and the efficacy of a maize bait containing 0.0025% brodifacoum in brown rat (*Rattus norvegicus*). XXX (unpublished). | TRIPLAN |  |  |  |  |
| B5 | B5.10.2/02 | XXX | XXX | Study on the palatability and efficacy of a 0.0025% brodifacoum corn bait in house mouse (*Mus musculus*). XXX  (unpublished). | TRIPLAN |  |  |  |  |
| B5 | B5.10.2/03 | XXX | XXX | Evaluation of the efficacy of a maize rodenticide (FANGA RAT-DICAL TECH) containing 0.0025% brodifacoum for the control of mouse infestation. One trial, 1 site: Rhone, France, 2012-2013. XXX (unpublished). | TRIPLAN |  |  |  |  |
| B5 | B5.10.2 | XXX | XXX | Efficacy evaluation of FANGA RAT-DICAL TECH (brodifacoum 0,0025% w/w a.i., crush corn bait) against Roof rat (*Rattus rattus* L.) in Italy | TRIPLAN |  |  |  |  |
| B5 | B5.10.2 | XXX | XXX | study on the palatability and efficacy of a 0.0025% w/w brodifacoum maize bait in brown rat (*Rattus norvegicus*) | TRIPLAN |  |  |  |  |
| B5 | B5.10.2 | XXX | XXX | Study on the palatability and efficacy of a 0.0025% w/w brodifacoum maize bait in black rat (*Rattus rattus*) | TRIPLAN |  |  |  |  |
| B5 | B5.10.2 | XXX | XXX | Efficacy evaluation of BDM25V1 (brodifacoum 0,0025% w/w a.i., corn bait) against Norway rat (*Rattus norvegicus* Berk.) in Italy | TRIPLAN |  |  |  |  |
| B5 | B5.10.2 | XXX | XXX | Efficacy evaluation of BDM25V1 (brodifacoum 0,0025% w/w a.i., corn bait) against Roof rat (Rattus rattus L.) in Italy | TRIPLAN |  |  |  |  |
| B5 | B5.10.2 | XXX | XXX | Efficacy evaluation of BDM25V1 (brodifacoum 0,0025% w/w a.i., corn bait)  against House mouse (*Mus musculus* L.) in Italy | TRIPLAN |  |  |  |  |
| B6 | B6.1.1 | XXX | XXX | FANGA BLOC SP PRO evaluation of acute oral toxicity in rats – acute toxic class method. XXX (unpublished). | TRIPLAN |  |  |  |  |
| B6 | B6.1.2 | XXX | XXX | FANGA BLOC SP PRO evaluation of acute dermal toxicity in rats. XXX (unpublished). | TRIPLAN |  |  |  |  |
| B6 | B6.2.1 | XXX | XXX | FANGA BLOC SP PRO assessment of acute dermal irritation. XXX  (unpublished). | TRIPLAN |  |  |  |  |
| B6 | B6.2.2 | XXX | XXX | FANGA BLOC SP PRO assessment of acute eye irritation. XXX  (unpublished). | TRIPLAN |  |  |  |  |
| B6 | B6.3 | XXX | XXX | FANGA BLOC SP PRO assessment of the skin sensitization potential in the mouse using the local lymph node assay (LLNA). XXX  (unpublished). | TRIPLAN |  |  |  |  |
| B6 | B6.4 | Colas S | 2011 | FAAR BLE evaluation of skin absorption: in vitro method (non GLP study). Phycher Bio-Développement, Study AC-PH-10/0247a-amended of the 6 June 2011.Non GLP, (unpublished). | TRIPLAN |  |  |  |  |
| B6 | B6.4 | Jäger, M | 2013 | ACTIPELLET-DIFE: In vitro dermal delivery with human skin | TRIPLAN |  |  |  |  |
| Add rows as necessary | | | | | | | | | |

Annex 3: Analytical methods residues – active substance

Brodifacoum

Date: 25.04.2013

Methods suitable for the determination of residues (monitoring methods)

Extract from document IIA of final CAR of brodifacoum.

Table 21: Analytical methods for the determination of brodifacoum residue

| Sample | **Test substance** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of determination** | **Reference** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Range | Mean | RSD |
| Soil | *Brodifacoum* | RP-HPLC/DAD (detection at 264 nm) | 0.016÷-0.16 mg/kg in soil, with 4 replicates per level | 0.256÷-12.8 μg/ml (0.006÷-0.32 mg/kg in soil), single determinations at 8 concentrations levels. r2 = 0.9999  No matrix-matched calibration | Not highly specific  LC/MS method for confirmation (only experimental conditions  provided) | 88.5÷-95.4 (overall) | 92.9 (overall) | 2.2 (overall) | LOQ = 0.016 mg/kg in soil  (lowest validated concentration level) | **IIIA4.2 (a)** |
| Drinking water *(natural mineral water Fiuggi)* | *Brodifacoum* | RP-HPLC with MS/MS detection.  Molecular ion (SIM): 521 (m/z), daughter ion (SRM): 187 (m/z)  Quantification by calibration curve, except for spiking level 0.05 μg/l (quantification with the lowest standard calibration level) | 0.05 μg/l (n=5) 0.5 μg/l (n=5) 5.0 μg/l (n=5) 50 μg/l (n=5) | 0.1÷-0.5 μg/ml  (0.05÷-0.25 μg/l in water),  4 determinations at 5 concentration levels  r = 0.995 (SIM mode)  r = 0.997 (SRM mode) | Highly specific | 83.5*÷-*92.0  77.7*÷-*94.1  72.3*÷-*94.6  83.2*÷-*107.7 | 87.8  82.5  81.7  97.8 | 3.8  7.2  9.8  10.6 | LOQ = 0.05 05 μg/l in drinking and ground water;  0.5 μg/l in surface water  (lowest validated concentration level)  LOD = 0.025 μg/l in water | **IIIA4.2 (c)** |
| Ground water  *(Well SB1 I.Pi.Ci)* | 0.05 μg/l (n=5) 0.5 μg/l (n=5) 5.0 μg/l (n=5) 50 μg/l (n=5) | 80.4*÷-*100.6  82.6*÷-*94.4  80.1*÷-*94.6  81.3*÷-*101.2 | 90.5  98.7  87.3  92.5 | 9.3  5.6  7.3  7.0 |
| Surface water *(sampled at Desenzano, Garda lake)* | 0.05 μg/l (n=5) 0.5 μg/l (n=5) 5.0 μg/l (n=5) 50 μg/l (n=5) | 116*÷-*124.3  79.5*÷-*88.0  78.7*÷-*98.6  104.6*÷-*117 | 120.6  84.5  87.3  110.8 | 2.9  4.5  7.8  3.6 |
| Blood serum  (*from Rabbit, lyophilized powder from clotted whole blood)* | *Brodifacoum* | RP-HPLC with MS/MS detection.  Molecular ion (SIM): 523 (m/z), daughter ion (SRM): 187 (m/z)  Quantification by calibration curve at 0.06 mg/l , quantification with the lowest standard calibration level at 0.3 mg/l | 0.06 mg/l (n=5)  0.3 mg/l (n=6) | 0.05-0.40 μg/ml  (0.05-0.40 mg/l in blood serum), 4 determinations at 5 concentration levels  r = 0.99679 (SIM mode)  r = 0.99623 (SRM mode | Highly specific | 80.8-96.6  86.2-109.1 | 92.1  101.7 | 6.5  8.6 | LOQ = 0.06 mg/l (lowest validated concentration level) | **IIIA4.2 (d)(2)** |
| Cucumber | *Brodifacoum* | LC/MS/MS.  Internal standard: Difenacoum  Linear calibration curve for all determinations, except for both spiking levels in lemon and for the validation in meat at 0.1 mg/kg (multi-level calibration standards used)  Brodifacoum  precursor ion 1: 521; product ion 1: 79;  precursor ion 2: 523; product ion 2: 81  *Coumatetralyl*  precursor ion 1: 291; product ion 1: 143; precursor ion 2: 291; product ion 2: 141  Product ion 1 used for measurements | 0.01 mg/kg (n=5)  0.1 mg/kg (n=5) | 0.03-1.2 μg/ml,  2 determinations at 4 concentration levels. Matrix-matched calibration solutions used  r2: 0.9095÷-0.9963 | Highly specific | 82-103  86-106 | 91  94 | 9  9 | LOQ = 0.01 mg/kg in all 5 matrices (lowest validated concentration level) | **IIIA4.3**  **[also IIIA4.2(d)(1) for Meat only]** |
| Wheat | 0.01 mg/kg (n=5)  0.1 mg/kg (n=5) | 88-126  71-90 | 107  84 | 13  9 |
| Meat | 0.01 mg/kg (n=5)  0.1 mg/kg (n=5) | 62-86  45-87 | 73  61 | 13  29 |
| Oil-seed rape | 0.01 mg/kg (n=5)  0.1 mg/kg (n=5) | 75-99  110-134 | 86  119 | 10  8 |
| Lemon | 0.01 mg/kg (n=5)  0.1 mg/kg (n=5) | 74-93  62-89 | 84  76 | 10  13 |

Annex 4: Toxicology and metabolism –active substance

Brodifacoum

Threshold Limits and other Values for Human Health Risk Assessment

Date: 31/07/2012

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 3.3 x 10-6 mg/kg bw/d | Develomental toxicity study in rats | 300 |
| AEL medium-term | 6.67 x 10-6 mg/kg bw/d | Maternal toxicity from developmental study in rabbits | 300 |
| AEL acute | 3.3 x 10-6 mg/kg bw/d | Reproductive 2-generation study in rats  Reproductive 2-generation study in rats | 300 |
| ADI | 3.3 x 10-6 mg/kg bw/d |
| ARfD | Not applicable |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption | 100% |
| Oral absorption | 75% |
| Dermal absorption | 0.647% |

| **Classification** | |
| --- | --- |
|  |  |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 1 H310  Acute Tox 1 H300  Acute Tox 1 H330  STOT RE Cat 1 H372  Repr 1A H360D  Repr. 1A; H360D: C ≥ 0,003 %  STOT RE 1; H372: C ≥ 0,02 %  STOT RE 2; H373: 0,002 % ≤ C < 0,02 % |

Annex 5: Toxicology – biocidal product

FANGA RAT-DICAL TECH

Date: 31/07/2012

|  |  |
| --- | --- |
| **General information** | |
| Formulation Type | Cereal grain bait (cracked corn) |
| Active substance(s) (incl. content) | Brodifacoum (0.0025% m/m) |
| Category |  |

| **Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)** | | | | |
| --- | --- | --- | --- | --- |
| Rat LD50 oral (OECD 420) | > 2 000 mg/kg bw |  |  |  |
| Rat LD50 dermal (OECD 402) | > 2 000 mg/kg bw |  |  |  |
| Rat LC50 inhalation (OECD 403) | No data submitted |  |  |  |
| Skin irritation (OECD 404) | Non irritant |  |  |  |
| Eye irritation (OECD 405) | Non irritant |  |  |  |
| Skin sensitisation (OECD 429; LLNA) | Non sensitizing |  |  |  |

| **Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)** | | | | |
| --- | --- | --- | --- | --- |
| Short-term toxicity studies | None |  |  |  |
| Toxicological data on active substance(s) (not tested with the preparation) | None |  |  |  |
|  |  |  |  |  |
| Toxicological data on non-active substance(s) (not tested with the preparation) | None |  |  |  |
|  |  |  |  |  |
| Further toxicological information | None | | | |

|  |  |
| --- | --- |
| **Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)** | |
|  |  |
| Regulation 1272/2008/EC | STOT RE 2 - H373 |

Annex 6: Safety for professional operators

FANGA RAT-DICAL TECH

Date: 31/07/2012

**Exposure assessment**

| Exposure scenarios for intended uses (Annex IIIB, point 6.6 ) |
| --- |

Primary exposure of professionals– FANGA RAT-DICAL TECH (exposure during cleaning considered) – Control of rats and mice

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Actual Dermal Total**  **[mg/kg/d]** | **InhalationExposure**  **[mg/m³]** | **Model** |
| **Control of rats and mice** | | | | | |
| Professionnal rat  (without gloves) | Brodifacoum | 56073-10-0 | 1.6x10-7 | Not applicable | CEFICstudy |

Risk assessment– Control of rats and mice

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **CAS** | **AEL [mg/kg/d]** | **Absorption**  **[%]** | | **Total syst exposure**  **[mg/kg bw/d]** | | Risk |
| inh | derm | Expo | %AEL |
| **Control of rats and mice** | | | | | | | | |
| Professionnal rat  (without gloves) | Brodifacoum | 56073-10-0 | 3.3x10-6 | 100 | 0.647 | 1.6x10-7 | 5 | Acceptable |

Annex 7: Safety for non-professional operators and the general public

FANGA RAT-DICAL TECH

| General information | |
| --- | --- |
| Formulation Type: | Cereal grain bait (cracked corn) |
| Active substance(s) (incl. content): | Brodifacoum (0.0025% m/m) |
| Category |  |
| Authorisation number |  |

| **Brodifacoum** |
| --- |

| Data base for exposure estimation | |
| --- | --- |
| according to | Appendix: Toxicology and metabolism – active substance/CAR |

| Exposure scenarios for intended uses (Annex IIIB, point 6.6 ) | |
| --- | --- |
| Primary exposure | Not applicable |
| Secondary exposure, acute | Infant ingesting bait |
| Secondary exposure, chronic | None |

**Conclusion:**

The accidental ingestion of baits poses a risk to infants since the AEL is exceeded when infant ingests more than 1.8 mg of product per day.

Annex 8: Residue behaviour

Brodifacoum

The intended uses description of the product FANGA RAT-DICAL TECH indicates that these uses are not relevant in terms of residues in food and feed. No further data are required concerning the residue behaviour.

Annex 9: Efficacy of the active substance from its use in the biocidal product

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Test substance** | **Test organism(s)** | **Test method** | **Test conditions** | **Test results: effects, mode of action, resistance** | **Reference\*** | **RI** |
| FANGA RAT-DICAL TECH  0.0025% brodifacoum | House mice (*Mus musculus)*  Brown rat *Rattus norvegicus* | Laboratory test  House mice: 10 animals (6 males and 4 females)  Brown rat: 10 animals (4 males and 6 females)  Intoxication duration: 20 days with daily measurement of mortality and food consumption. | Acclimation: 7 days in individual cage.  D0-D5: routine food has been given:  40.0 g for rats, 10.0 g for mice.  D6-D20: routine food and tested baits have been given in different feeding dishes.  40.0 g of routine food and 40.0 g of tested baits for rats  10.0 g of routine food and 10.0 g of tested baits for mice.  Food and bait consumption were measured and mortality was observed during 20 days after the first day of intoxication. | The FANGA RAT-DICAL TECH bait containing 25 ppm brodifacoum given to 10 house mice (6 males and 4 females) and to 10 brown rats (4 males, 6 females) during 20 days demonstrated that:  For brown rats: The studied bait did not appear as palatable enough for obtaining good performance against brown rat.  Mean palatability percentage on brown rat = 2.87 %  Mortality percentage on brown rat = 20 %  Efficacy can be considered as insufficient for brown rats in the conditions of the test.  For house mice: The studied bait did not appear as palatable enough for obtaining good performance against house mouse.  Mean palatability percentage on house mouse = 20.15%  Mortality percentage on house mouse = 70 %.  Efficacy can be considered as moderate for house mice. | XXX | 3 |
| FANGA RAT-DICAL TECH  0.0025% brodifacoum | Brown rats  *(Rattus norvegicus)* | Laboratory test:  Brown rats:  5 males and 5 females.  Intoxication duration: 4 days with daily measurement of mortality and consumption. | Acclimatization: 4 days in individual cage at room temperature.  Day 0: reference food and bait biocidal product have been given:  - 50 g per animal of reference food for the assessment of palatability,  - 50 g per animal of paste bait for the assessment of efficacy  during 4 consecutive days with daily consumption measurements.  Mortality was observed during 21 days every 24 hours. | The FANGA RAT-DICAL TECH bait containing 25 ppm brodifacoum given to brown rats (5 males and 5 females) during 4 days has demonstrated:   * A palatability equivalent to 0.29 (29 %) * Bait consumption half less than the reference item for all rats between day 0 and day 4 * A very good efficacy with a mortality of 100 % in a period from day 5 to day 10 | XXX | 1 |
| FANGA RAT-DICAL TECH  0.0025% brodifacoum | House mice  *(Mus musculu*s) | Laboratory test  House mice:  10 males and 10 females.  Intoxication duration: 4 days with daily measurement of mortality and consumption. | Acclimatization: 4 days in separate cages (10 males in a cage and 10 females in a second cage) at room temperature.  Day 0: reference food and bait biocidal product have been given during 4 consecutive days with daily consumption measurements.  Mortality was observed during 21 days every 24 hours or until the death of all animals. | The FANGA RAT-DICAL TECH bait containing 25 ppm brodifacoum given to house mice (10 males and 10 females) during 4 days has demonstrated:   * A palatability equivalent to 0.28 (28%) * Not a very good consumption (especially for females) between day 0 and day 4 * A good efficacy with a mortality of 100 % in a period from day 7 to day 11 | XXX | 1 |
| FANGA RAT-DICAL TECH  0.0025% brodifacoum | House mice  *(Mus musculu*s) | Field test: small farm  The rodenticide was evaluated using the census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites. | Acclimatization: 14 days (150-200 g of semolina per station per day)  Treatment : 50 g of maize bait in each lockable bait station (total 10 bait stations) during11 days  Post-baiting: 5 days  (150-200 g of semolina per station per day)  Mortality was observed from the first day of intoxication and noted about every 2 days until the end of the trial. | The FANGA RAT-DICAL TECH bait containing 25 ppm brodifacoum given to House mice has demonstrated:  The efficacy was total (100%).   * Pre-baiting plateau = 140 g/day * Post-baiting = 0 g * Assessed efficacy = 100%   The assessed bait has been very well accepted by house mice and effective and the results are consistent with laboratory ones (100 % efficacy).  No secondary poisoning occurred at the baited site. | XXX | 1 |

Annex 9bis: Efficacy of the active substance from its use in the biocidal product 2016

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test substance | Test organisms | Test system / Concentrations applied / exposure time | Test conditions | Test results: effects, mode of action, resistance | Reference |
| FANGA RAT-DICAL TECH  0.0025% brodifacoum | Black rat  (*Rattus rattus*) | Field study  EPPO PP1/114(2) | Method for recording / scoring effects: daily bait take and tracking score during the trial period  The percentage of efficacy of the test product against the rat population was calculated using the following formula:  % efficacy = 100 – [ Post-treatment rat population size index/Pre-treatment rat population size index x 100]  where:  Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.  Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.  - Intervals of examination: every day from 2013-11-06 to 2013-12-27 | The trial was set up in an agricultural habitat (chicken breeding stable) showing an adjoining large hangar for the parking of camper vans and equipment storage. In both the buildings rats infestation was signalled by the owner.  The site was surveyed and a notable rats presence was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Roof rat (Rattus rattus L.).  Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings.  In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rat population size during a Pre-treatment census (monitoring of the daily consumption of unpoisoned placebo baits).  On the same way it was calculated an index of the rat population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned placebo baits during the Post-treatment phase).  According to the results of the present study, FANGA RAT-DICAL TECH showed a high acceptance level and provided a complete effectiveness (100,0%) against the Rattus rattus population present across the trial site. | XXX |
| FANGA RAT-DICAL TECH  0.0025% brodifacoum | Brown rat (*Rattus norvegicus*) | Laboratory study  Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products »  Brown rats:  5 males and 5 females.  Intoxication duration: 4 days with daily measurement of mortality and consumption. | Acclimatization: 4 days in individual cage at room temperature.  Day 0: reference food and bait biocidal product have been given during 4 consecutive days with daily consumption measurements.  Mortality was observed during 21 days every 24 hours. | The FANGA RAT-DICAL TECH bait containing 25 ppm brodifacoum given to brown rats (5 males and 5 females) during 4 days according to the Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products » has demonstrated:   * A palatability equivalent to 0.35 * A low consumption between day 0 and day 4 * A good efficacy with a mortality of 90% in a period from day 3 to day 12 | XXX |
| FANGA RAT-DICAL TECH  0.0025% brodifacoum | Black rat (*Rattus rattus*) | Laboratory study  Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products »  Black rats:  5 males and 5 females.  Intoxication duration: 4 days with daily measurement of mortality and consumption. | Acclimatization: 4 days in individual cage at room temperature.  Day 0: reference food and bait biocidal product have been given during 4 consecutive days with daily consumption measurements.  Mortality was observed during 21 days every 24 hours. | The FANGA RAT-DICAL TECH bait containing 25 ppm brodifacoum given to black rats (5 males and 5 females) during 4 days according to the Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products » has demonstrated:   * A palatability equivalent to 0.40 * A good consumption between day 0 and day 4 * A good efficacy with a mortality of 90% in a period from day 7 to day 11 | XXX |
| FANGA RAT-DICAL TECH  0.0025% brodifacoum | Brown rats (*Rattus norvegicus*) | Field study  EPPO PP1/114(2) | Method for recording / scoring effects: daily bait take and tracking score during the trial period  The percentage of efficacy of the test product against the rat population was calculated using the following formula:  % efficacy = 100 – [ Post-treatment rat population size index/Pre-treatment rat population size index x 100]  where:  Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.  Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.  - Intervals of examination: every day from 2015-01-02 to 2015-02-12 | The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses) in which rats infestation was signalled by the farmer.  The farm site was surveyed and a notable rats presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Norway rat (Rattus norvegicus Berk.).  Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside or outside the buildings.  In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rat population size during a Pre-treatment census (monitoring of the daily consumption of unpoisoned census baits).  On the same way it was calculated an index of the rat population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned census baits during the Post-treatment phase).  According to the results of the present study, BDM25V1 aged of two years showed a good acceptance level and provided a complete effectiveness (100,0%) against the Rattus norvegicus population present across the trial site. | XXX |
| FANGA RAT-DICAL TECH  0.0025% brodifacoum | Black rats (*Rattus rattus*) | Field study  EPPO PP1/114(2) | Method for recording / scoring effects: daily bait take and tracking score during the trial period  The percentage of efficacy of the test product against the rat population was calculated using the following formula:  % efficacy = 100 – [ Post-treatment rat population size index/Pre-treatment rat population size index x 100]  where:  Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.  Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.  - Intervals of examination: every day from 2015-01-02 to 2015-02-11 | The trial was set up in an agricultural habitat (fodder and equipment warehouses) in which rats infestation was signalled by the farmer.  The farm site was surveyed and a notable rats presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Roof rat (Rattus rattus L.).  Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings.  In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rat population size during a Pre-treatment census (monitoring of the daily consumption of unpoisoned census baits).  On the same way it was calculated an index of the rat population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned census baits during the Post-treatment phase).  According to the results of the present study, BDM25V1 aged of two years showed a good acceptance level and provided a complete effectiveness (100,0%) against the Rattus rattus population present across the trial site. | XXX |
| FANGA RAT-DICAL TECH  0.0025% brodifacoum | House mice (*Mus musculus*) | Field study  EPPO PP1/114(2) | Method for recording / scoring effects: daily bait take and tracking score during the trial period  The percentage of efficacy of the test product against the rat population was calculated using the following formula:  % efficacy = 100 – [ Post-treatment rat population size index/Pre-treatment rat population size index x 100]  where:  Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.  Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.  - Intervals of examination: every day from 2015-01-02 to 2015-02-12 | The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses) in which mice infestation was signalled by the farmer.  The farm site was surveyed and a notable mice presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these animals to be identified as belonging to House mouse (Mus musculus L.).  Eight bait-stations and eight tracking patches were set out on the main mice runways which were found inside the buildings.  In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the mice population size during a Pre-treatment census (monitoring of the daily consumption of unpoisoned census baits).  On the same way it was calculated an index of the mice population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned census baits during the Post-treatment phase).  According to the results of the present study, BDM25V1 showed a good acceptance level and provided a complete effectiveness (100,0%) against the Mus musculus population present across the trial site. | XXX |

* **Minor change 2017**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **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, outdoor, open areas, waste dumps and landfills | FANGA B+ RONGEUR  (BDB10V1)  0.001% w/w  Brodifacoum | *Mus musculus* | Field study  EPPO PP 1/114(2)  Census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites. | Acclimatization: 16 days (150-200 g of wheat per station per day)  Treatment: 100 g of bait per day in each lockable bait station –total 8 bait stations) during13 days  Post-baiting: 7 days  (100 g of wheat per station per day) | Estimated efficacy = 100 %.  Pre-baiting plateau = 453,5 g/day  Post-baiting = 0 g  R.I. =1 | XXX |
| Rodenticide | Indoor, outdoor, open areas, waste dumps and landfills | FANGA B+ RONGEUR  (BDB10V1)  0.001% w/w Brodifacoum | Brown rats  *Rattus norvegicus*  5 males  5 females | Laboratory study  Method based on:  Technical Notes for Guidance on Product Evaluation – Product type 14  Brown rat: 10 animals (5 males and 5 females)  Intoxication duration:  4 days with daily measurement of mortality and food consumption | Acclimatization: 4 days in individual cage at room temperature.  Day 0: reference food and bait biocidal product have been given:  - 50 g per animal of reference food for the assessment of palatability,  - 50 g per animal of biocidal product during 4 consecutive days with daily consumption measurements.  Mortality was observed during 21 days every 24 hours or until the death of all animals. | Palatability = 69 %  Mortality = 90 %  in a period from day 4 to day 9  R.I. =1 | XXX |
| Rodenticide | Indoor, outdoor, open areas, waste dumps and landfills | FANGA B+ RONGEUR  (BDB10V1)  0.001% w/w Brodifacoum | Brown rats  *Rattus norvegicus* | Field study  EPPO PP 1/114(2)  Census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites. | Acclimatization: 15 days (200 g of wheat per station per day)  Treatment: 200 g of bait per day in each lockable bait station –total 8 bait stations) during 17 days  Post-baiting: 6 days  (200 g of wheat per station per day) | Estimated efficacy = 100 %  Pre-baiting plateau = 1298.3 g/day  Post-baiting = 0 g  R.I. =1 | XXX |
| Rodenticide | Indoor, outdoor, open areas, waste dumps and landfills | FANGA B+ RONGEUR  (BDB10V1)  0.001% w/w Brodifacoum | Black rats  *Rattus rattus*  5 males  5 females | Laboratory study  Method based on:  Technical Notes for Guidance on Product Evaluation – Product type 14  Brown rat: 10 animals (5 males and 5 females)  Intoxication duration:  4 days with daily measurement of mortality and food consumption | Acclimatization: 4 days in individual cage at room temperature.  Day 0: reference food and bait biocidal product have been given:  - 50 g per animal of reference food for the assessment of palatability,  - 50 g per animal of biocidal product during 4 consecutive days with daily consumption measurements.  Mortality was observed during 21 days every 24 hours or until the death of all animals. | Palatability = 41 %  Mortality = 90 %  in a period from day 4 to day 7  R.I. =1 | XXX |
| Rodenticide | Indoor, outdoor, open areas, waste dumps and landfills | FANGA B+ RONGEUR  (BDB10V1)  0.001% w/w Brodifacoum | Black rats  *Rattus rattus* | Field study  EPPO PP 1/114(2)  Census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites. | Acclimatization: 17 days (200 g of wheat per station per day)  Treatment: 200 g of bait per day in each lockable bait station –total 8 bait stations) during 16 days  Post-baiting: 6 days  (200 g of wheat per station per day) | Estimated efficacy = 100 %  Pre-baiting plateau = 1022.3g/day  Post-baiting = 0 g  R.I. =1 | XXX |

1. In case the product would have more than one name, all names can be provided in this field. [↑](#footnote-ref-1)
2. According to Regulation (EC) 1272/2008, or where relevant, Directive 1999/45/EC. This section shall only include precautionary statements triggered by the CLP legislation. In accordance with paragraph 8 of document CA-May13-Doc.5.4, a precautionary statement that has been proven unnecessary in the risk assessment because of the intended use of the product should be left out of the SPC and of the label. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-2)
3. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-3)
4. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-4)
5. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-5)
6. Data which have not been already submitted for the purpose of the Annex I inclusion. [↑](#footnote-ref-6)