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

NA – MIC Case Number in R4BP : BC-QX033191-16

NA – MIC Case Number in R4BP : BC-PQ039643-16

Evaluating Competent Authority: France

NA - MIC Date : 13/04/2018

NA – MIC Date :

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**History of the dossier** (**updated PAR – 2018)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 |
| NA-MIC | FR | BC-PQ039643-16 | xx/xx/xxxx | Reduced use rates for target organisms rats. Uprgrade of shelf-life. Packaging modification. Addition of commercial names.  Modification of manufacturing sites.  Addition of 5 new manufacturing sites. |

**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 |

**Minor Change 2018 :**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Users** | **Target organisms** | **Application rate** | **Field of use** | **Packagings** |
| Professionals | Rat *(Rattus norvegicus and rattus ratts)* | 100 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*) | 100 g / bait point separated by 5-10 meters | In and around buildings  Open areas | Individual sachets  /PE:  Maximum pack size: 150 g |
| Mice (*Mus musculus*) | 40 g / bait point separated by 1-2 meters | Indoor |

# 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.

* **Minor Change 2018**

The minor change on FANGA RONGEUR PRO 25 consists in a reduction of use rates for target organisms rats (*Rattus rattus* and *Rattus norvegicus*) at 100g per bait station every 5 to 10 meters. The minor change also consists in an upgrade of shelf-life to 24 months, of packagings modifications, an addition of commercial names, modification of manufacturers names and address and the addition of 5 manufacturers.

## 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).
* **Minor change 2018**

**Physico chemical properties and analytical methods**

The new packaging are acceptable.

The justification on the ambient storage stabilty to extend the shelf life to 24 months has been provided. Variations after 79 months storage are below 10%. However, the applicant should clarify why differences among the results at 24 and 79 months are so different.

**Efficacy data**

The following efficacy studies were submitted:

* A field test was carried out with rats (*Rattus norvegicus*), with exposure to 4 years and 11 months aged formulation of FANGA B+ RONGEUR (0.001 % brodifacoum).
* A field test was carried out with rats (*Rattus rattus*), with exposure to 4 years and 11 months aged formulation of 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)

**Minor change 2018**

The applicant has submitted a minor change application in order to add additional packaging. The following description includes packagings that have been authorized as well as additional packagings claimed in the frame of the minor change.

* The product FANGA RONGEUR PRO 25 is supplied in PE/PP sachets (Rats : 10-20-25-30-40-50-60-90-100g) (Mice : 10-20-30-40g) wrapped in :
* Buckets-Barrel PP/PE (5-10-15-18-20-25-30kg)
* Paper bags with or without plastic film PE/PP inside (5-10-15-20-25-30kg)
* PE/PP bags-film (5-10-15-20-25kg)
* Metal box (5-10-15-20-25kg)
* Cardboard box (5-10-12-15-20-25-30-50kg)
* Bait station PET/PP/PE/PVC

The product FANGA RONGEUR PRO 25 is supplied in bulk in:

* Buckets-Barrel PP/PE (5-10-15-18-20-25-30kg)
* paper bags with or without plastic film PE/PP inside (5-10-15-20-25-30kg)
* PE/PP bags-film (5-10-15-20-25kg)
* Metal box (5-10-15-20-25kg)
* Carton box (5-10-12-15-20-25-30-50kg)
* Bait station PET/PP/PE/PVC
* Non-Professionals users : The product FANGA RONGEUR PRO 25 is supplied in PE/PP sachets (Rats : 10-20-25-30-40-50-60-90-100g) (Mice : 10-20-30-40g) wrapped in :
* Cardboard box, PE/PP Film, Metal box, Flacon PE/PP, Buckets PE/PP, until 150 grams.
* Bait station PET/PP/PE/PVC

The new packagings are covered by the previous assessment and are acceptable.

## 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** |

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| --- |
| **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. |

**Minor change 2018**

The applicant has submitted a minor change application in order to increase the shelf life up to 24 months.

The following statement was submitted:

“FANGA RONGEUR PRO 25 (Internal code BDB25V1) is a rodenticide wheat bait containing 0.0025% of brodifacoum and 0.001% of denatonium benzoate.

The detailed composition of this bait is the same as the baits FANGA B+ RONGEUR (internal code: BDB10V1) and FANGA RONGEUR PRO (Internal code: BDB50V1) already authorized in France.

The only difference between those products is the concentration of brodifacoum (CAS N°56073-10-0), FANGA B+ RONGEUR contains 0.001% of brodifacoum, FANGA RONGEUR PRO contains 0.005% of brodifacoum and FANGA RONGEUR PRO 25 contains 0.0025% of brodifacoum. Therefore FANGA RONGEUR PRO 25 is intermediate bait between FANGA B+ RONGEUR and FANGA RONGEUR PRO. So the physical-chemical tests conducted on FANGA B+ RONGEUR and FANGA RONGEUR PRO regarding to the shelf-life (24-months) can be extrapolated to FANGA RONGEUR PRO 25.

A storage stability test - long term storage at ambient temperature1 (2 years / 20°C) was performed on the product FANGA B+ RONGEUR. With this report, the shelf-life of 2 years has been proved. Moreover, a storage stability test - long term storage at ambient temperature2 (2 years / 20°C) was performed on the product FANGA RONGEUR PRO and an extraction of active substance (brodifacoum) of a product aged of 79 months was performed in order to proof the long stability. Because the product FANGA RONGEUR PRO is stabled after 79 months; the shelf-life of 24 months at ambient temperature is proved. Those studies gave excellent results (long stability at ambient temperature), we can then conclude that FANGA RONGEUR PRO 25, wheat containing 0.0025% brodifacoum, has a shelf-life of 24 months.”

Results provided in the PAR FANGA RONGEUR B+ are summarized below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***B3.4 Storage stability, stability and shelf-life*** | | | | | |
| ***B3.4.1 Storage stability tests*** | | | | | |
| ***B3.4.1.1 – Accelerated storage study (2 weeks at 54°C)*** | *Storage stability of FANGA B+ RONGEUR for 14 days at 54°C ± 2°C*  *CIPAC MT 46.3* | *FANGA RONGEUR B+*  *0.00854g/kg brodifacoum*  *Batch 25/11* | ***Aspect***  *Before the accelerated storage procedure for 14 days at 54±2°C:*  *Blue/green/wheat grains in intact transparent plastic bag (PE) Slight odour of grain.*  *Polypropylene bucket of 1 kg closed with a green PE lid to clip. Ø :± 22 cm, h : ± 14.5 cm.*  *Well closed bucket without deterioration or special anomaly.*  *No observable sign of test item contamination on the outer surface. No leak during shaking or turning. No noticeable odour before opening of the package.*  *Weight bag: 955.6g*  *After the accelerated storage procedure for 14 days at 54±2°C:*  *Blue/green wheat grains in intact transparent plastic bag (PE).*  *Polypropylene bucket of 1 kg closed with a green PE lid to clip. Ø :± 22 cm, h : ± 14.5 cm.*  *Well closed bucket without deterioration or special anomaly.*  *No observable sign of test item contamination on the outer surface. No leak during shaking or turning. No noticeable odour before opening of the package.*  *Weight bag: 948.5g*  ***DW=-0.7%***  ***Conclusion****: No modification of the appearance or no significant pack weight change after an accelerated storage procedure for 14 days at 54 ±2 °C.* | *22718-First Interim Report* | ***Acceptable. Packaging is stable after accelerated storage in PP packaging.*** |
|  | *HPLC Defitraces Report n°11-920010-027 AMD* | *FANGA RONGEUR B+*  *0.00854g/kg brodifacoum*  *Batch 25/11* | ***Analytical quantification of brodifacoum***  *Before the accelerated storage procedure for 14 days at 54±2°C:*  *The content of brodifacoum was 0.000854 ± 0.000040% w/w. (mean of 3 determinations, RSD (1.88%)< Horwitz value (7.76%))*  *After the accelerated storage procedure for 14 days at 54±2°C:*  *The content of brodifacoum was 0.000779 ± 0.000067% w/w. (mean of 3 determinations, RSD (3.48%) < Horwitz value (7.87%))*  *A significant change**was observed in the content of brodifacoum in FANGA B+ RONGEUR**(-8.8% deviation from T = 0 value) after the accelerated storage**procedure for 14 days at 54 ± 2 °C.*  *The applicant states: FANGA B+ RONGEUR is a grain bait essentialy made of cereal. Content of active substance brodifacoum in the product is very low (0.01g/kg, 10ppm). The product is considered heterogeneous and variations of active substance content (>5%) cannot be explained as a degradation since in the 2 years shelf life study it has been demonstrated that the variation is not linear.* | *22718-First Interim Report* | ***Acceptable***  ***Variation of brodifacoum: -8.8% (limit 5%)***  ***Variations can be due to the heterogeneity of the product and to the adsorption of the a.i on the grain.***  ***The method used for the determination of brodifacoum is validated.*** |
|  | *MT 59.4 method (1995)* | *FANGA RONGEUR PRO*  *Bodifacoum*  *0.049 g/kg*  *Batch 22/11* | *Before the accelerated storage procedure (storage 8 weeks at 40°C):*   |  |  | | --- | --- | | ***Test sieve*** | ***Mass of residue (g)*** | | ***250µm*** | ***100.0*** | | ***125µm*** | ***<0.1*** | | ***Collecting pan*** | ***<0.1*** |   *The dust content was lower than 0.1%.*   |  |  | | --- | --- | | ***Test sieves*** | ***% or residue*** | | ***5.6mm*** | ***<0.1*** | | ***4.0mm*** | ***1.4*** | | ***2.8mm*** | ***90.2*** | | ***2.0mm*** | ***7.8*** | | ***Collectin pan*** | ***0.6*** |   *The majority of the particles (90.2%) of the test item were between 2 mm and 2.8 mm.*  *After the accelerated storage procedure*   |  |  | | --- | --- | | ***Test sieve*** | ***Mass of residue (g)*** | | ***250µm*** | ***100.0*** | | ***125µm*** | ***<0.1*** | | ***Collecting pan*** | ***<0.1*** |   *The dust content was lower than 0.1%.*   |  |  | | --- | --- | | ***Test sieves*** | ***% or residue*** | | ***5.6mm*** | ***<0.1*** | | ***4.0mm*** | ***0.8*** | | ***2.8mm*** | ***89.4*** | | ***9.5*** | ***7.8*** | | ***Collectin pan*** | ***0.8*** |   *The majority of the particles (90.2%) of the test item were between 2 mm and 2.8 mm.* | *12-920010.008* | ***Read across is acceptable.*** |
|  | *Method CIPAC MT 78* | *BDB10V1 (FANGA B+ RONGEUR), batch 01/15* | *Appearance before and after accelerated storage 14 days at 54°C: blue/green grains of wheat, white opaque PP bucket (no significant change)*  *Attrition beefore and after accelerated storage 14 days at 54°C: 100%* | *15-920010-003* | ***Acceptable*** |
| ***B3.4.1.2 –******Ambient shelf life study*** | *CropLife No 17* | *FANGA RONGEUR B+*  *0.00854g/kg brodifacoum*  *Batch 25/11* | *Before storage:*  *Intact transparent PE bags containing 50g of grains, dust free*  *Colour: blue green*  *Odour: slight odour of grain*  *After the procedure of storage for:*  *2 years:*  *No change in the appearance of the packaging (primary packaging: PE bag containing 50g of grains / secondary packaging: PP bucket of 1kg).*  *Colour: blue green*  *Odour: slight odour of grain* | *22718-Final Report [[1]](#footnote-1)* | ***Acceptable. The product is stable in PE bags.*** |
|  | *HPLC Defitraces Report n°11-920010-027 AMD* | *FANGA RONGEUR B+*  *0.00854g/kg brodifacoum*  *Batch 25/11* | ***Quantitative analysis of Brodifacoum***  *Initial active substance content: 8.54± 0.4% w/w.*  *After the procedure of storage for 16 months:*  *Active substance content: 8.55 ± 0.23 mg/kg*  *Difference :* ***+ 0.1%***  *After the procedure of storage for 2 years:*  *Active substance content: 6.16 ± 1.01 mg/kg*  *Difference :* ***- 27.8%***  ***Conclusion:*** *No change in the appearance and in the mass oft he packaging after 2 years of stiorage****.***  *Significant change in the active ingredient after 2 years of storage*  *The applicant states: FANGA B+ RONGEUR is a grain bait essentialy made of cereal. Content of active substance brodifacoum in the product is very low (0.01g/kg, 10ppm). The product is considered heterogeneous and variations of active substance content (>5%) cannot be explained as a degradation since variations of active substance brodifacoum with time were not linear. Therefore for this product, it can be assumed that the variations are not related to a degradation of the active substance.*   |  |  |  |  | | --- | --- | --- | --- | | *Product tested* | *determination T1* | *determination T2* | *determination T3* | | *FANGA B+ rongeur*  *(cereal :wheat)* | *14 days* | *16 months* | *24 months* | | *-8,8%* | *+0,1%* | *-27,8%* | | *22718-Final Report* | ***Acceptable. The variations of active substance content can be due to the heterogeneity of the product and to the adsoprtion of the a.i on the grain.*** |

***Conclusion:***

*The product*

*FANGA B+ RONGEUR is a cereal bait ready-to-use rodenticide.*

*Considering the small changes of composition and the non-physico-chemical classification of formulants, physico-chemical properties of FANGA RONGEUR PRO can be extrapolated to FANGA B+RONGEUR.*

*FANGA B+ RONGEUR is not flammable, not autoflammable up to 400°C, has no explosive properties and no oxidizing properties. It is not dusty (nearly dust free).*

*No change appeared in the appearance of the biocidal product or the packaging after storage procedures for 14 days at 54 ±2 °C and 2 years at ambient temperature in PE sachets. A significant change was observed in the content of Brodifacoum in FANGA B+ RONGEUR (-27.8 % deviation from T=0 value) after 2 years of storage. Nevertheless, it has been demonstrated that the variations were not linear during storage stability and cannot be related to a degradation of the active substance. It can be due to the heterogenity of the product. FR considers that the product is stable after accelerated and long term storage. The product is stable in PE sachets and therefore is compatible with all claimed packaging. Technical properties were not changed after storage.*

*The active subtance is sensitive to light. Therefore, the product must be store away from light.*

*FANGA B+ RONGEUR is not classified for physico-chemical properties.*

***Shelf life: 2 years***

For the product FANGA RONGEUR PRO, the applicant has also submitted a minor change application with the following statement and results:

In the renewal assessment, eCA has granted a shelf life of 12 months since above the time point, decrease of a.i content was higher than 10% (-20.4%) and no justification during the renewal assessment was provided to explain such variations.

The applicant has now provided the following statement:

“A storage stability test - long term storage at ambient temperature was provided to the authorities to obtain a shelf-life of 24 months for the product FANGA RONGEUR PRO[[2]](#footnote-2). Because the variations of the active substance (brodifacoum) in the product after 24 months was above the tolerance of 10 % (deviation of -20.4% / T0), authorities haven’t accepted to deliver an authorization for the product FANGA RONGEUR PRO with a shelf-life of 24 months. By receiving the new authorization after the renewal time, TRIPLAN has decided to analyze a sample of product FANGA RONGEUR PRO, aged of 79 months and stored at room temperature. After an extraction of the active substance (brodifacoum) by a BPL laboratory, the deviation was only - 6.1 % / T0. That proves the stability of the product FANGA RONGEUR PRO during 79 months[[3]](#footnote-3). With this result and because the shelf-life of 79 months was proved, we can thus conclude the shelf-life of 24 months for the product FANGA RONGEUR PRO.”

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| Storage stability test – **long term storage at ambient temperature** | CIPAC 46.3  2-years storage stability | FANGA RONGEUR PRO  (0.005% w/w of brodifacoum)  Batch N° 22/11 | Determination of physico-chemical properties and storage stability test packed in PE film bag:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | Initial | After 6 months | After 12 months | After 24 months at rt | After 79 months | | Appearance | Blue/Green/Purple wheat grains | Blue/Green/Purple wheat grains | Blue/Green/Purple wheat grains | Blue/Green/Purple wheat grains | / | | Appearance of packaging | Transparent PE bags | Transparent PE bags | Transparent PE bags | Transparent PE bags | / | | Content of AS | 0.0049% | 0.0046% | 0.0045% | 0.0039% | 0.0046% | | Variation of AS (%) | - | -6.1% | -8.2% | -20.4% | -6.1% | | Difference of weight (%) |  | -2.3% | -2.5% | -3.8% | / | | pH value (CIPAC 75.3) | 6.46 |  |  | 7.97 | / |   Quantification of AS has been done by HPLC UV detection with the method evaluated in the PAR. | B. Demangel, 07 May 2018, report N° 11-920010-026 amended |

**eCA**:

The comparison between each product FANGA RONGEUR PRO (0.005% w/w AS), FANGA RONGEUR PRO 25 (0.0025% w/w AS) and FANGA B+ RONGEUR (0.001% w/w AS) is presented in the confidential PAR.

FANGA B+ RONGEUR was previously considered stable after 2 years (PAR FANGA B+ RONGEUR)

Fanga rongeur pro was considered stable after 2 years during an on-going dossier based on data presented above.

Therefore, as FANGA RONGEUR PRO 25 have an AS content composition situated between FANGA B+ RONGEUR and FANGA RONGEUR PRO and the rest of composition is quite similar, eCA accepts to increase the shelf life from one to two years with a requirement that for renewal of the product, a complete acceptable shelf life study on fanga rongeur pro 25 need to be submitted.

### 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.

* **Minor change 2018**

To support the efficacy of the new claimed application rate for the use against rat, the applicant has submitted two field tests with the product FANGA B+ RONGEUR.

The main difference between both products is the concentration of active substance: FANGA B+ RONGEUR contains 0.001 % w/w of brodifacoum and FANGA RONGEUR PRO 25 contains 0.0025% w/w of brodifacoum, other components are the same to nearly the same concentrations. Therefore efficacy studies conducted with FANGA B+ RONGEUR are acceptable to demonstrate the efficacy of FANGA RONGEUR PRO 25.

All efficacy studies results are presented in annex 9 and the compositions of all tested products are presented in the confidential part of the PAR.

Submitted efficacy data are compliant with the requirements of the TNsG PT14 (2009) and the results of these tests are respecting the criteria of the TNsG PT14 (2009).

French competent authorities (FR CA) consider that the elements presented in the dossier confirm the efficacy of the product FANGA RONGEUR PRO 25 against rats (*Rattus norvegicus* and *Rattus rattus*) at the claimed application rate of 100 g / bait point:

### 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 |

* **Minor change 2018**

French competent authorities (FR CA) considers that the elements presented in the dossier confirm the efficacy of the product FANGA RONGEUR PRO 25 against rats (*Rattus norvegicus* and *Rattus rattus*) at the claimed application rate of 100 g / bait point:

* For professional users: in and around buildings, and waste dumps.
* For non professional users: in and around buildings.

### 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

* **Minor change 2018**

French competent authorities (FR CA) assessed that the product FANGA RONGEUR PRO 25 has shown a sufficient efficacy for the control of rats (*Rattus norvegicus* and *Rattus norvegicus*) in and around buildings by professional and non professional users and, in waste dumps and landfills by professional users only with a shelf-life of two years.

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*): 100 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)[[4]](#footnote-4)** | *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[[5]](#footnote-5)**

|  |  |
| --- | --- |
| **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[[6]](#footnote-6)  - *[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***

|  |
| --- |
| - 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***

|  |
| --- |
| - 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***

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**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***

|  |
| --- |
| - 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***

|  |
| --- |
| - 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***

|  |
| --- |
| - 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***

|  |
| --- |
|  |

**4.3. Use description**

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

|  |  |
| --- | --- |
| **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***

|  |
| --- |
| - 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***

|  |
| --- |
| - 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***

|  |
| --- |
| - 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)* – House mice – General Public– 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) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations[[7]](#footnote-7) |
| **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** | 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***

|  |
| --- |
| - 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***

|  |
| --- |
|  |

***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***

|  |
| --- |
| - 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***

|  |
| --- |
|  |

***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– Rats – General Public – indoor**

|  |  |
| --- | --- |
| **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** | General Public |
| **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***

|  |
| --- |
| - 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**

|  |  |
| --- | --- |
| **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[[8]](#footnote-8). |
| **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**

|  |  |
| --- | --- |
| **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***

|  |
| --- |
| - 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. |

# Proposal for decision – Minor Change 2018

1. **Administrative information**

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

| **Trade name(s)[[9]](#footnote-9)** | FANGA RONGEUR PRO 25 |
| --- | --- |
|  | BRODIGRAIN RAT 25  BRODIGRAIN RONGEUR 25  SUPP‘ BRODIGRAIN 25  STOP BRODIGRAIN 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** | RATOUCY SAS |
| **Address of manufacturer** | RATOUCY SAS  29 rue de la foret – LOOZE - Bp 145  89303 Joigny Cedex  France |
| **Location of manufacturing sites** | RATOUCY SAS  29 rue de la foret – LOOZE - Bp 145  89303 Joigny Cedex  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | AEDES PROTECTA |
| **Address of manufacturer** | 75 rue d’Orgemont  95210 Saint-Gratien  France |
| **Location of manufacturing sites** | Lieu-dit Douillac  81310 Parisot  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | *FARMAVIT OOD* |
| **Address of manufacturer** | Bul Tsar Boris III, n°63, 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** | 16 rue Claude Chappe  ZAE 2000  97829 Le Port CEDEX  France |
| **Location of manufacturing sites** | 35 Chemin Lartin  97435 SAINT GILLES LES HAUTS  France |

|  |  |
| --- | --- |
| **Nom du fabricant** | *FARMA-CHEM SA* |
| **Adresse du fabricant** | *Industrial Area of Sindos, P.O. Box 1026 Block 53 Zone C*  *57022 Thessaloniki*  *Greece* |
| **Emplacement des sites de fabrication** | *Industrial Area of Sindos, P.O. Box 1026 Block 53 Zone C*  *57022 Thessaloniki*  *Greece* |

|  |  |
| --- | --- |
| **Nom du fabricant** | *AGROZA AGROTECHNICAL LTD* |
| **Adresse du fabricant** | *AITOLIAS 2 & EL. VENIZELOU 158*  *16341 Athens*  *Greece* |
| **Emplacement des sites de fabrication** | *AITOLIAS 2 & EL. VENIZELOU 158*  *16341 Athens*  *Greece* |

|  |  |
| --- | --- |
| **Nom du fabricant** | *AGROLOGY SA* |
| **Adresse du fabricant** | *P.O. Box1089, Industrial Area of Thessaloniki*  *57022 Thessaloniki*  *Greece* |
| **Emplacement des sites de fabrication** | *P.O. Box1089, Industrial Area of Thessaloniki*  *57022 Thessaloniki*  *Greece* |

|  |  |
| --- | --- |
| **Nom du fabricant** | *FHS* |
| **Adresse du fabricant** | *Rue de la Tête de Loup – ZAC de Grandchamp*  *77440 Ocquerre*  *France* |
| **Emplacement des sites de fabrication** | *Rue de la Tête de Loup – ZAC de Grandchamp*  *77440 Ocquerre*  *France* |

|  |  |
| --- | --- |
| **Nom du fabricant** | *SALOMEZ* |
| **Adresse du fabricant** | *ZI Av. Du Général de GAULLE*  *89130 Toucy*  *France* |
| **Emplacement des sites de fabrication** | *ZI Av. Du Général de GAULLE*  *89130 Toucy*  *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**

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

* **3. Hazard and precautionary statements[[10]](#footnote-10)**

|  |  |
| --- | --- |
| **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: | Warning |
| 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[[11]](#footnote-11)  - *[Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  - Rats (*Rattus norvegicus* and *Rattus rattus*): 100 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/PP (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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE/PP (5;10; 15; 20; 25; 30 kg) * PE or 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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg) |

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

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| --- |
| - 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**

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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)** | 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*): 100 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/PP (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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE/PP (5;10; 15; 20; 25; 30 kg) * PE or 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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg) |

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

|  |
| --- |
| - 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***

|  |
| --- |
| - 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 *-*  Mice and/or 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*): 100 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   Sachets are packed in:   * Paper bags, several layers with one or without plastic film in PE/PP (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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE/PP (5;10; 15; 20; 25; 30 kg) * PE or 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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg) |

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

|  |
| --- |
| - 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***

|  |
| --- |
| - 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[[12]](#footnote-12) |
| **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 10-20-30-40g PE or PP sachet   Sachets are packed in:   * Paper bags, several layers with one or without plastic film in PE/PP (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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE/PP (5;10; 15; 20; 25; 30 kg) * PE or 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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg) |

***4.4.1.* *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.  - *[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**

|  |  |
| --- | --- |
| **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*): 100 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/PP (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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE/PP (5;10; 15; 20; 25; 30 kg) * PE or 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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg) |

***4.5.1.* *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.  - *[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*): 100 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/PP (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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE/PP (5;10; 15; 20; 25; 30 kg) * PE or 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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg) |

***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- *(not relevant in France*) – Mice and/or Rats – professionals – Outdoor open areas & waste dumps**

|  |  |
| --- | --- |
| **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*): 100 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/PP (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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg)   FANGA RONGEUR PRO 25 is also supplies in loose in:   * Paper bags, several layers with one or without plastic film in PE/PP (5;10; 15; 20; 25; 30 kg) * PE or 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) * Metal box (5 ; 10 ; 15 ; 20 ; 25kg) * PE/PP bag (5 ; 10 ; 15 ; 20 ; 25kg) |

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

|  |
| --- |
| - 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].* |

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

|  |
| --- |
| - 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. |

***4.7.3 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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| - 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. |

***4.7.4 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 – 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[[13]](#footnote-13). |
| **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: 10-20-30-40g 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) * PE/PP flacon (up to 150g) |

***4.8.1.* *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. |

***4.8.2 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 – indoor**

|  |  |
| --- | --- |
| **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*): 100 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) * PE/PP flacon (up to 150g) * Bait box in plastic PET/PP/PE/PVC (40g ; 100g) |

***4.9.1.* *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. |

***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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**4.10. Use description**

**Table 10. Use # 10 – Rats – general public – 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)** | *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*): 100 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) * PE/PP flacon (up to 150g) * Bait box in plastic PET/PP/PE/PVC (40g; 100g) |

***4.10.1.* *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. |

***4.10.2 Use-specific risk mitigation measures***

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***4.10.3 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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***4.10.4 Where specific to the use, the instructions for safe disposal of the product and its packaging***

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***4.10.5. 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: 2 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[[14]](#footnote-14) submitted in support of the evaluation of the active substance

No new datda has been provided.

##### 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** |
| B5 |  | Rovetto I | 2017 | Efficacy evaluation of BDB10V1 (brodifacoum 0,0010% w/w a.i., blue wheat bait – aged formulation) against Norway rat (Rattus norvegicus Berk.) in Italy, 2074.BCD.SAG17 | TRIPLAN |  |  |  |  |
| B5 |  | Rovetto I | 2017 | Efficacy evaluation of BDB10V1 (brodifacoum 0,0010% w/w a.i., blue wheat bait – aged formulation) against Roof rat (Rattus rattus L.) in Italy, 2075.BCD.SAG17 | TRIPLAN |  |  |  |  |

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

* **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 |

* **Minor change 2018**

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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  4 years and 11 months aged formulation | Brown rats  *Rattus norvegicus*  Estimated population: 40 - 50 rats | 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 (100 g of maize grain per station per day)  Treatment: 100 g of bait per day in each lockable bait station – total 8 bait stations) during 18 days  Post-baiting: 6 days  (100 g of maize grain per station per day) | Estimated efficacy = 100 %  Pre-baiting plateau =800 g/day  Post-baiting = 0 g  R.I. =1 | Rovetto I.  2017  2074.BCD.SAG17 |
| Rodenticide | Indoor, outdoor, open areas, waste dumps and landfills | FANGA B+ RONGEUR  (BDB10V1)  0.001% w/w Brodifacoum  4 years and 11 months old | Black rats  *Rattus rattus*  Estimated population: 45 - 50 rats | 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 (100 g of maize grain per station per day)  Treatment: 100 g of bait per day in each lockable bait station – total 8 bait stations) during 19 days  Post-baiting: 6 days  (100 g of maize grain per station per day) | Estimated efficacy = 100 %  Pre-baiting plateau = 721.5g/day  Post-baiting = 0 g  R.I. =1 | Rovetto I.  2017  2075.BCD.SAG17 |

1. de Ryckel B. 2014. Physical and chemical properties and storage stability of FANGA B+ RONGEUR FINAL REPORT Analysis on the test item as received after 14 days at 54°C ± 2°C and after 16 months and 2 years at 20°C ± 2°C. Centre wallon de Recherches agronomiques, Report n° 22718 of 29 April 2014, GLP. [↑](#footnote-ref-1)
2. B. Demangel, 14 March 2014, report N° 11-920010-026, “Physico-chemical tests and chemical stability after a storage procedure for 2 years at 20 ± 2 °C on FANGA RONGEUR PRO”. [↑](#footnote-ref-2)
3. B. Demangel, 07 May 2018, report N° 11-920010-026 amended “Physico-chemical tests and chemical stability after a storage procedure for 2 years at 20 ± 2 °C on FANGA RONGEUR PRO”. [↑](#footnote-ref-3)
4. In case the product would have more than one name, all names can be provided in this field. [↑](#footnote-ref-4)
5. 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-5)
6. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-6)
7. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-7)
8. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-8)
9. In case the product would have more than one name, all names can be provided in this field. [↑](#footnote-ref-9)
10. 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-10)
11. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-11)
12. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-12)
13. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-13)
14. Data which have not been already submitted for the purpose of the Annex I inclusion. [↑](#footnote-ref-14)