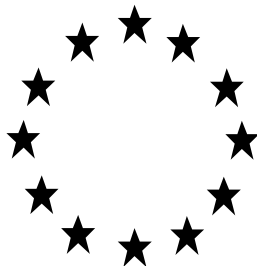


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



FANGA 5 CEREALES 25

Product type 14

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

Case Number in R4BP: BC-BM069618-25

Evaluating Competent Authority: France

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Note to the reader:

**Disclaimer regarding general information**

This consolidated PAR for the minor change of the product authorisation FANGA 5 CEREALES 25 is based on the PAR of reference product FANGA RAT-DICAL TECH granted by FR on 2014, in which all addenda have been included before FANGA 5 CEREALES 25 authorization.

In part 1 and 2 of this consolidated PAR:

- Each section contains the initial assessment and the subsequent successive assessments (major change and post authorisation data) in a chronological order. These assessments are pointed out with specific titles corresponding to the type of application and the year at which they were delivered.
- The assessments related to the minor change of the product are indicated at the end of each section and are highlighted in grey.

In part 3 of the consolidated PAR “proposal for decision”: the summary of product characteristics corresponding to the decision for the minor change.

**Disclaimer regarding user category**

For the risk assessment of PT14, two user categories have been addressed depending on the quantity of manipulated product and the possibility of using PPE: non-professional users and professional users.

In France, any professional user needs a dedicated national certificate, hence it is expected that he/she has the required competence to access to biocidal products that are authorized for professional users they are thus considered as « trained professional users ».

Consequently, in the SPC for renewal in Part 3, uses for “professionals” are mentioned according to the agreed standard SPC, but they are not relevant in France. In case of mutual recognitions, it is proposed that each cMS adapts the conditions of authorization of the product according to its own legislation.

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

<b>Application type</b>	<b>refMS</b>	<b>Case number in the refMS</b>	<b>Decision date</b>	<b>Assessment carried out (i.e. first authorisation / amendment /renewal)</b>
NA-APP	FR		30/09/2014	Initial assessment FANGA RAT DICAL TECH
NA-ADC	FR	BC-EQ250069-31	19/12/2016	Addition of others trades names and manufacturers of the product
NA-MAC And post-authorisation requirement	FR	BC-WG017333-42	18/05/2016	Amendement of the authorisation, addition of: <ul style="list-style-type: none"> <li>- general public use</li> <li>- outdoor uses</li> <li>- target organisms;</li> <li>- trade name;</li> <li>- manufacturers of the product</li> <li>- packaging for professional (loose):</li> </ul> Post-authorisation: shelf-life and efficacy data.
NA-RNL	FR	BC-AV018542-30	09/03/2018	Renewal of the authorisation
NA-MIC	FR	BC-AB038305-68	20/08/2018	Amendement of the authorisation: <ul style="list-style-type: none"> <li>- reduction of use rates against rats,</li> <li>- modification of packagings size,</li> <li>- addition of trade names,</li> <li>- modification and addition of manufacturers sites.</li> </ul>
NA-BBS	FR		07/05/2019	Authorization of same biocidal product FANGA 5 CEREALES 25
NA-MIC	FR	BC-BM069618-25	24/08/2022	Minor change application : <ul style="list-style-type: none"> <li>- Modification of the composition</li> <li>- Trade names added</li> <li>- Administrative changes</li> </ul>

## CONCLUSION

⇒ **MINOR CHANGE 2022**

### **INTRODUCTION OF THE APPLICATION**

France, as e-CA, received an application from TRIPLAN for a minor change of authorisation for the biocidal product FANGA 5 CEREALES 25.

FANGA 5 CEREALES 25 is a biocidal product with type of product 14 for the control of rodents (house mice and rats) based on 0,0025% (technical w/w) brodifacoum. The biocidal product is a ready-to-use bait (grain), and is currently to be applied indoor and outdoor by professional or non-professional users.

The minor change request concerns :

- Composition modifications
- Administrative changes

### **SUMMARY AND OVERALL CONCLUSION OF THE ASSESSMENT**

#### **Physico-chemical properties**

Accelerated storage stability and additional characteristics of the new composition of the product were provided and show that the new composition is stable at temperature below 40°C and have the similar physical chemical characteristics.

The ongoing long-term stability storage should be provided in the frame of the renewal of the product.

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

#### **Efficacy**

The product **FANGA 5 CEREALES 25** has shown sufficient efficacy and can be used for the control of mice (*Mus musculus*) and rats (*Rattus norvegicus* and *Rattus rattus*) at the claimed application rate of 40 g / bait station for mice and 100 g / bait station for rats, with a shelf-life up to 2 years:

- For professional users: in and around buildings, and outdoor environments (open areas, and waste dumps);
- For non-professional users: indoor (mice and rats) and around buildings (rats only).

#### **Substance of concern**

No substance of concern has been identified in the frame of the new formulation. Please see the confidential annex for further details.

#### **Human health**

Minor change is covered by the assessment of exposure performed in the first authorization.

The conclusions of risk assessment of the biocidal product family remain unchanged.

**Environment**

The biocidal product does not contain any substance of concern. Minor change is covered by the risk assessment for the environment performed in the first authorization.

The conclusions of risk assessment for the environment of the biocidal product remain unchanged.

**Overall conclusion**

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the biocidal product family FANGA 5 CEREALES 25 in the frame of the minor change has been demonstrated.

**Authorised uses (0.0025% of brodifacoum)**

<b>Users</b>	<b>Target organisms</b>	<b>Application rate</b>	<b>Field of use</b>	<b>Packagings</b>
Professionals	Rat ( <i>Rattus norvegicus and rattus rattus</i> )	200 g / bait point separated by 5-10 meters	In and around buildings Open areas Waste dumps and landfills	Individual sachets in PE And loose
	Mice ( <i>Mus musculus</i> )	40 g of product / bait station at separated to 1-2 meters		Minimum pack size: 5 kg
Non professional s	Rat ( <i>Rattus norvegicus and rattus rattus</i> )	200g / bait point separated by 5-10 meters	In and around buildings	Individual sachets in PE
	Mice ( <i>Mus musculus</i> )	40 g / bait point separated by 1-2 meters	Indoor buildings	Maximum pack size: 150 g

**Intended uses for minor change 2018 (0.0025 % of brodifacoum)**

<b>Users</b>	<b>Target organisms</b>	<b>Application rate</b>	<b>Field of use</b>	<b>Packagings</b>
Professionals & trained professionals	Rat ( <i>Rattus norvegicus and rattus rattus</i> )	100 g / bait point separated by 5-10 meters	In and around buildings Open areas Waste dumps and landfills	Individual sachets in PE And loose
	Mice ( <i>Mus musculus</i> )	40 g of product / bait station at separated to 1-2 meters		Minimum pack size: 5 kg
Non professional s	Rat ( <i>Rattus norvegicus and rattus rattus</i> )	100 g / bait point separated by 5-10 meters	In and around buildings	Individual sachets in PE Maximum pack



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	Mice ( <i>Mus musculus</i> )	40 g / bait point separated by 1-2 meters	Indoor	size: 150 g
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**Intended uses for minor change 2022 (0.0025 % of brodifacoum)**

<b>Users</b>	<b>Target organisms</b>	<b>Application rate</b>	<b>Field of use</b>	<b>Packagings</b>
Professionals & trained professionals	Rat ( <i>Rattus norvegicus and rattus rattus</i> )	100 g / bait point separated by 5-10 meters	In and around buildings Open areas Waste dumps and landfills	Individual sachets in PE And loose  Minimum pack size: 5 kg
	Mice ( <i>Mus musculus</i> )	40 g of product / bait station at separated to 1-2 meters		
Non professional s	Rat ( <i>Rattus norvegicus and rattus rattus</i> )	100 g / bait point separated by 5-10 meters	In and around buildings	Individual sachets in PE  Maximum pack size: 150 g
	Mice ( <i>Mus musculus</i> )	40 g / bait point separated by 1-2 meters	Indoor	

## 1 General information about the product application

### 1.1 Applicant

<b>Company Name:</b>	TRIPLAN SA
<b>Address:</b>	BP258 La Poste Française
<b>City:</b>	Andorre la Vieille
<b>Postal Code:</b>	AD500
<b>Country:</b>	Principauté d'Andorre
<b>Telephone:</b>	+376 741 445
<b>Fax:</b>	+376 741 450
<b>E-mail address:</b>	triplan@andorra.ad

#### 1.1.1 Person authorised for communication on behalf of the applicant

<b>Name:</b>	Fredy Lacroux
<b>Function:</b>	Managing director
<b>Address:</b>	BP258 La Poste Française
<b>City:</b>	Andorre la Vieille
<b>Postal Code:</b>	AD500
<b>Country:</b>	Principauté d'Andorre
<b>Telephone:</b>	+376741 445
<b>Fax:</b>	+376 741 450
<b>E-mail address:</b>	saida.triplan@andorra.ad

➤ **Renewal (2017)**

The current e-mail address is triplan@andorra.ad

### 1.2 Proposed authorisation holder

<b>Company Name:</b>	TRIPLAN SA
<b>Address:</b>	BP258 La Poste Française
<b>City:</b>	Andorre la Vieille
<b>Postal Code:</b>	AD500
<b>Country:</b>	Principauté d'Andorre
<b>Telephone:</b>	+376 741 445
<b>Fax:</b>	+376 741 450
<b>E-mail address:</b>	triplan@andorra.ad
<b>Letter of appointment for the</b>	No

applicant to represent the authorisation holder provided (yes/no):	
--	--

### 1.3 Information about the product application

Application received:	02/02/2012
Application reported complete:	16/03/2012
Type of application:	Product authorisation
Further information:	

### 1.4 Information about the biocidal product

#### 1.4.1 General information

Trade name:	FANGA RAT-DICAL TECH
Manufacturer's development code number(s), if appropriate:	SOFAR
Product type:	14 - rodenticide
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Active substance's identity and content: Brodifacoum 0.0025% w/w
Formulation type:	Cereal grains (crushed corn) bait
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); If yes: authorisation/registration no. and product name: or Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):	No           No

#### 1.4.2 Information on the intended use(s)

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

<b>Overall use pattern (manner and area of use):</b>	Indoor environment (public and private buildings, farms.)
<b>Target organisms / stages:</b>	I.1.1 Murids : <i>Muridae</i> I.1.1.1 Brown rat: <i>Rattus norvegicus</i> I.1.1.2 Roof rat, House rat: <i>Rattus rattus</i> I.1.1.3 House mouse: <i>Mus musculus</i>
<b>Category of users:</b>	V.2 Professional
<b>Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:</b>	<p>VI.2 Covered application VI.2.1 in bait stations</p> <p>FANGA RAT-DICAL TECH is intended to be used for control of mice, brown rats and black rats in buildings included farm buildings. The treatment with FANGA RAT-DICAL TECH is applied by trained professional users.</p> <p>The product is ready-to-use (cereal grains) so with no dilution and no other substances added for application. It is always supplied in sachets and manually applied in secured bait stations</p> <p><u>Rats</u> : 180-200 g grains/secured bait point separated by 5-10 m. <u>Mice</u> : 50 g grains/secured bait point separated by 1-2 m.</p> <p>Over a period of 28 days for application, cleaning, refilling and collect of dead rodents. The control of rats and mice is carried out inside buildings, so the environmental conditions in which rodents are found tend to be similar relating to geographical areas.</p>
<b>Potential for release into the environment (yes/no):</b>	Yes
<b>Potential for contamination of food/feedingstuff (yes/no)</b>	No
<b>Proposed Label:</b>	<p>FANGA RAT-DICAL TECH is intended to be used for control of mice, brown rats and black rats in buildings included farm buildings. The treatment with FANGA RAT-DICAL TECH is applied by trained professional users.</p> <p><u>Rats</u> : 180-200 g grains/secured bait point separated by 5-10 m. <u>Mice</u> : 50 g grains/secured bait point separated by 1-2 m.</p> <p>Hazard symbol: None</p> <p>Risk phrases: None</p> <p>Safety phrases: S1/2: Keep locked up and out of reach of children. S7: Keep container tightly closed. S13: Keep away from food, drink and animal feeding stuffs. S20/21: When using do not eat, drink or smoke. S24: Avoid contact with skin S35: This material and its container must be disposed of in a safe way</p>

	S36/37: Wear suitable protective clothes and gloves. S46: If swallowed, seek medical advice immediately (show label if possible). S49: Keep only in original container Do not reuse empty containers.
<b>Use Restrictions:</b>	Use only indoors in secured bait stations out of reach of children and domestic animals.

For full details of the intended uses claimed by the applicant, please see Annex 0a.

### 1.4.3 Information on active substance

<b>Active substance chemical name:</b>	Brodifacoum
<b>CAS No:</b>	56073-10-0
<b>EC No:</b>	259-980-5
<b>Purity (minimum, g/kg or g/l):</b>	950 g/kg
<b>Inclusion directive:</b>	2010/10/CE
<b>Date of inclusion:</b>	9 February 2010
<b>Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):</b>	No
<b>Manufacturer of active substance(s) used in the biocidal product:</b>	PM TEZZA SRL <sup>1</sup>
<b>Company Name:</b>	PM TEZZA SRL
<b>Address:</b>	Via Tre Ponti 22
<b>City:</b>	S. Maria di Zevio (VR)
<b>Postal Code:</b>	37050
<b>Country:</b>	Italy
<b>Telephone:</b>	
<b>Fax:</b>	
<b>E-mail address:</b>	

According to the Assessment Report Revised in November 2010, the technical equivalence between the two sources of the Task Force has not been demonstrated. As the Activa's source is not recognized, only an authorized source must be used.

### Renewal 2017

#### COMPARATIVE ASSESSMENT

Brodifacoum does meet the exclusion criteria laid down in Article 5(1)(c) of Regulation (EU) No 528/2012. Brodifacoum does meet the conditions laid down in Article 10(1)(a) and (e) of Regulation (EU) No 528/2012 if approved, and is therefore considered as a candidate for

<sup>1</sup> Activa is the applicant of the active substance but not the manufacturer. Tezza SRL is the manufacturer of the active substance as mentioned in the Final CAR of brodifacoum of the Activa / PelGar Brodifacoum Task Force.

substitution.

A comparative assessment has been carried out at the European level. According to Article 1 of Commission Implementing Decision (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council. In the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled. Therefore, the authorisation of this product will be renewed for 5 years.

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

There is no substance of concern.

### 1.5 Documentation

#### 1.5.1 Data submitted in relation to product application

##### Identity, physico-chemical and analytical method data

Physico-chemical properties studies and analytical methods on the biocidal product FANGA RAT-DICAL TECH were provided by TRIPLAN.

##### ➤ Minor change application ( FANGA RAT-DICAL TECH) - 2018

No additional data was provided in the frame of the minor change of the product authorisation. The minor change consists in an addition of packagings. See dedicated part (part 2.2.4) for details.

##### ➤ Minor change application (FANGA 5 CEREALES 25)- 2021

New studies have been provided: the measurement of some physico-chemical properties, an accelerated storage study and the validation data of the analytical method for the determination of the active substance content.

##### Efficacy data

The following efficacy studies were submitted:

For the initial dossier:

- A free-choice laboratory test was carried out with house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*), with exposure to **FANGA RAT-DICAL TECH** (0.0025 % w/w brodifacoum) for 20 days. The age of the product is not known.
- A free-choice laboratory test was carried out with rats (*Rattus norvegicus*), with exposure to a 2 month aged formulation of **FANGA RAT-DICAL TECH** (0.0025 % w/w brodifacoum) for 4 days.

- A free-choice laboratory test was carried out with house mice (*Mus musculus*), with exposure to a 2 month aged formulation of **FANGA RAT-DICAL TECH** (0.0025 % w/w brodifacoum) for 4 days.
- A field test was carried out with house mice (*Mus musculus*), with exposure to a 2 month aged formulation of **FANGA RAT-DICAL TECH** (0.0025 % w/w brodifacoum).

➤ **Major change application - 2016**

**Efficacy data**

The following efficacy studies were submitted:

- A free-choice laboratory test was carried out with brown rats (*Rattus norvegicus*), with exposure to FANGA RAT-DICAL TECH (0.0025 % brodifacoum Maize bait) fresh bait for 4 days.
- 
- A free-choice laboratory test was carried out with black rats (*Rattus rattus*), with exposure to FANGA RAT-DICAL TECH (0.0025 % brodifacoum Maize bait) fresh bait for 4 days.
- 
- A field test (Italy) was carried out with house mice (*Mus musculus*), with exposure to aged bait FANGA RAT-DICAL TECH (0.0025 % brodifacoum Maize bait).
- 
- A field test (Italy) was carried out with brown rats (*Rattus norvegicus*), with exposure to aged bait FANGA RAT-DICAL TECH (0.0025 % brodifacoum Maize bait).
- 
- A field test (Italy) was carried out with black rats (*Rattus rattus*), with exposure to aged bait FANGA RAT-DICAL TECH (0.0025 % brodifacoum Maize bait).
- 
- A field test (Italy) was carried out with black rats (*Rattus rattus*), with exposure to FANGA RAT-DICAL TECH (0.0025 % brodifacoum Maize bait) fresh bait.

➤ **Minor change application ( FANGA RAT-DICAL TECH) - 2018**

- A field test was carried out with black rats (*R. rattus*), with exposure to a 5 years aged formulation of FANGA RAT-DICAL TECH
- A field test was carried out with brown rats (*R. norvegicus*), with exposure to a 5 years aged formulation of FANGA RAT-DICAL TECH

➤ **Minor change application (FANGA 5 CEREALES 25)- 2021**

The following efficacy studies were submitted:

- A field test (Italy) was carried out with brown rats (*Rattus norvegicus*), with exposure to aged bait (43 months) FANGA 5 CEREALES 25 (0.0025 % brodifacoum 5 cereals bait).
- A field test (Italy) was carried out with black rats (*Rattus rattus*), with exposure to aged bait (43 months) FANGA 5 CEREALES 25 (0.0025 % brodifacoum 5 cereals bait).
- A field test (Italy) was carried out with house mice (*Mus musculus*), with exposure to aged bait (43 months) FANGA 5 CEREALES 25 (0.0025 % brodifacoum 5 cereals bait).
- A field test (Italy) was carried out with black rats (*Rattus rattus*), with exposure to aged bait (51 months) FANGA 5 CEREALES 25 (0.0025 % brodifacoum 5 cereals bait).
- A free-choice laboratory test was carried out with house mice (*Mus musculus*), with exposure to FANGA 5 CEREALES 25 (0.0025 % brodifacoum 5 cereals bait) aged bait for 39 months.
- A free-choice laboratory test was carried out with brown rats (*Rattus norvegicus*), with exposure to FANGA 5 CEREALES 25 (0.0025 % brodifacoum 5 cereals bait) aged bait for 39 months.

**Toxicology data**

The applicant submitted new toxicological data on active substance and studies for the product (see corresponding sections). A new percutaneous absorption study (*in vitro*) has been submitted by TRIPLAN for difenacoum and results were extrapolated to brodifacoum.

#### **Residue data**

No new study has been submitted for the biocidal product authorisation.

#### **Ecotoxicology data**

No new study has been submitted for the biocidal product authorisation.

#### ➤ **Renewal application - 2017**

For the renewal of authorization, no additional data has been submitted.

### **1.5.2 Access to documentation**

As stated in the letter of access granted by Activa to Triplan:

*Activa S.r.l, (via Feltre 32, Milano-Italy), as Notifier and having rights on all the data included in the Dossier for Brodifacoum (CAS No: 56073-10-0) presented by The Activa/Pelgar Brodifacoum and Difenacoum Task Force (composed by: Activa/Tezza S.r.l and Pelgar International Ltd) for Annex I listing to RMS Italy **authorises** the France competent authorities to use these data for authorisation purpose TRIPLAN (BP 258 Poste Francaise - AD500 Andorre la Vieille - PRINCIPAT D'ANDORRA) for the product **FANGA RAT-DICAL TECH (PT14)**.*

Please refer to the LoA for the complete list of studies for which access has been granted.

#### ➤ **Major change application - 2016**

For the major change of authorization, no additional LOA has been submitted.

#### ➤ **Renewal application - 2017**

For the renewal of authorization, no additional LOA has been submitted.



## 2 Summary of the product assessment

The product is to be used in tamper-resistant bait boxes or covered bait stations.

"Tamper-resistant bait boxes" are meant to be tamper-resistant devices, that prevent the access to the baits for children and non-target animals, and that protect the baits from bad weather.

"Covered bait stations" are meant to be devices with the same level of security for the human beings and the environment than the security provided by tamper-resistant bait boxes, fastened to prevent any removal, made in order to avoid direct contact of the bait with the environment. This device must be designed to keep baits out of reach of the general public and non-target animals, and to protect the bait from bad weather

It is considered that professional users only (on the contrary to the general public) are able to design such covered bait stations.

### 2.1 Identity related issues

The source of the active substance used in the biocidal product FANGA RAT-DICAL TECH is not the same as the source used for annex I inclusion. The technical equivalence is in progress and evaluated by Italy. Only a recognized source of active substance can be used in the product FANGA RAT-DICAL TECH<sup>2</sup>. Refer to the confidential annex for more details.

#### ➤ Renewal application - 2017

The source of the active substance used in the biocidal product FANGA RAT DICAL TECH is not the same as the source used for annex I inclusion. The technical equivalence has been evaluated and accepted by IT.

### 2.2 Classification, labelling and packaging

#### 2.2.1 Harmonised classification of the active substance

Classification - Regulation (EC) 1272/2008	
Hazard statement	Acute Tox. 1
	Acute Tox. 2
	STOT RE 1
	Aquatic Acute 1
	Aquatic Chronic 1
Precautionary statements	H310      Fatal in contact with skin.
	H300      Fatal if swallowed.

<sup>2</sup> Assessment Report of Brodifacoum, November 2010, Revision 2 (Italy).

	H372	Causes damage to organs through prolonged or repeated exposure.
	H400	Very toxic to aquatic life.
	H410	Very toxic to aquatic life with long lasting effects.

➤ **Renewal application - 2017**

<b>Classification - Regulation (EC) 1272/2008</b>		
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 %	

**2.2.2 Classification of the biocidal product**

<b>Classification - Directive 67/548/EEC</b>	
Class of danger	None
R phrases	None
S phrases	None

<b>Classification - Regulation (EC) 1272/2008</b>	
Hazard statement	None

Precautionary statements	None
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➤ **Renewal application - 2017**

<b>Classification - Regulation (EC) 1272/2008</b>	
Hazard category	STOT RE 2
Hazard statements	H373: May cause damage to organs (blood) through prolonged or repeated exposure
Precautionary 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)].

**2.2.3 Labelling of the biocidal product**

<b>Labelling - Directive 67/548/EEC</b>	
Symbols:	None
Indications of danger:	None
Risk phrases:	None
Safety phrases:	None

➤ **Renewal application - 2017**

<b>Labelling - Regulation (EC) 1272/2008</b>	
Pictograms:	
Signal words:	Warning
Hazard statements:	H373: May cause damage to organs (blood) through prolonged or repeated exposure

**2.2.4 Packaging of the biocidal product**

**Packaging accepted by FR during the evaluation of the reference biocidal product** FANGA RAT-DICAL TECH:

For non professional, FANGA RAT-DICAL TECH is supplied in:

- 25; 50; 100 and 200g polyethylene sachets for rats;
- 25 and 50g polyethylene sachets for mice.

**Sachets are packed in:**

- Polypropylene bucket (5; 10; 15; 18 and 20kg);
- Carton (5; 10 and 20kg);
- Paper bag (20 and 25kg).

➤ **Major change application - 2016**

**For the major change, new packagings have been claimed by the applicant:**

**For professionals**

FANGA RAT-DICAL TECH is supplied in:

- Rats: 25; 50; 100 and 200g polyethylene sachets
- Mice 20; 40g polyethylene sachets

Sachets are packed in:

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

FANGA RAT-DICAL TECH is also supplies in loose:

- Paper bags, several layers with one or without plastic film in PE (5;10;15;20;25 kg)
- Polyethylene bucket (5; 10; 15; 18; 20 kg)
- Carton (5; 10; 12; 15; 20; 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; 1.2; 1.3; 1.4; 1.5kg)
- Bait box in plastic PET/PP/PE/PVC (up to 1.5 kg)

**For non-professionals**

FANGA RAT-DICAL TECH is supplied in:

- Rats: 25; 50; 100 and 200g polyethylene sachets
- Mice: 20; 40g polyethylene sachets

Sachets are packed in:

- Polyethylene bucket (0.1; 0.2; 0.3; 0.4; 0.5; 0.6; 0.7; 0.8; 0.9; 1; 1.2; 1.3; 1.4; 1.5 kg)
- Carton (0.1; 0.2; 0.3; 0.4; 0.5; 0.6; 0.7; 0.8; 0.9;1;1.2; 1.3; 1.4; 1.5kg)
- Metal box without lacquer (0.1; 0.2; 0.3; 0.4; 0.5; 0.6; 0.7; 0.8; 0.9; 1; 1.2; 1.3; 1.4; 1.5 kg)
- Bait box in plastic PET/PP/PE/PVC (up to 1.5kg)
- polyethylene containers (0.1; 0.2; 0.3; 0.4; 0.5; 0.6; 0.7; 0.8; 0.9;1;1.2; 1.3; 1.4; 1.5 kg)

The product is compatible with all new claimed packaging as biocidal product is a solid. No further data are required

➤ **Renewal application – 2017**

For the renewal, the existing authorized packagings are claimed and validated.

Packaging will be adapted based on re-approval regulation conditions.

For non professional users, the packaging is limited to 150g for rats and 50 for mice. Given the validated doses (200g for rats and 40g for mice), bait boxes will be authorised only for mice.

➤ **Minor change application – 2018**

For the minor change, new packagings have been claimed by the applicant and validated (*italic*):

**For professionals**

FANGA RAT-DICAL TECH is supplied in:

- Rats: 10, 20, 25, 50, 100 g PE/PP sachets
- Mice: 10, 20, 40 g PE/PP sachets

Sachets are packed in:

- Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg)
- *PE/PP bucket* (5-10-15-20-25 kg)
- PE/PP bags (5-10-15-20-25 kg)
- Carton box (5-10-12-15-20-50 kg)
- Metal box without lacquer (5-10-15-20-25 kg)
- Prefilled tamper resistant PET/PP/PE/PVC bait station

FANGA RAT-DICAL TECH is also supplies in loose:

- Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg)
- *PE/PP buckets* (5-10-15-20-25 kg)
- *PE/PP bags* (5-10-15-20-25 kg)
- Carton box (5-10-12-15-20-50 kg)
- Metal box without lacquer (5-10-15-20-25 kg)
- Prefilled tamper resistant PET/PP/PE/PVC bait station

**For non-professionals**

FANGA RAT-DICAL TECH is supplied in:

- Rats: 10, 20, 25, 50, 100 g PE/PP sachets
- Mice: 10, 20, 40 g PE/PP sachets

Sachets are packed in:

- *PE/PP bucket* (up to 150 g)
- Carton box (up to 150 g)
- *PE/PP film* (up to 150 g)
- Metal box without lacquer (up to 150 g)
- *PE/PP containers* (up to 150 g)
- Prefilled tamper resistant PET/PP/PE/PVC bait box

## **2.3 Physico/chemical properties and analytical methods**

### **2.3.1 Active ingredient**

#### **2.3.1.1 Identity, origin of active ingredient**

The source of the active substance used in the biocidal product FANGA RAT-DICAL TECH is not the source used for annex I inclusion. The technical equivalence is in progress and

evaluated by Italy. Only a recognized source of active substance can be used in the product FANGA RAT-DICAL TECH. Refer to the confidential annex for more details.

A letter of access to brodifacoum data from Activa has been provided.

➤ **Renewal application - 2017**

The source of the active substance used in the biocidal product FANGA RAT DICAL TECH is not the same as the source used for annex I inclusion. The technical equivalence has been evaluated and accepted by IT.

**2.3.1.2 Physico-chemical properties**

Physical and chemical properties of the active substance have already been evaluated at EU level and are presented in the CAR of the active substance brodifacoum (2010). The applicant TRIPLAN has a letter of access to these data.

**Source CAR 2010 (Document I):**

Brodifacoum is an off-white powder at 20°C and atmospheric pressure, with a relative density of 1.53. It was observed to darken and decompose at 235.8°C, whereas no decomposition or transformation occurred below 150°C.

Brodifacoum is non-volatile, with a Henry's Law Constant value of 2.35E-18 Pa.m<sup>3</sup>.mol<sup>-1</sup>. It is essentially insoluble in water at pH 5, but its solubility proved to increase with pH, due to the variation of the ionisation degree of the 4-hydroxycoumarin group in pH range under investigation (5-9). Brodifacoum also turned out to be soluble in organic solvents; results showed that solubility did not vary with temperature, except for dichloromethane.

Brodifacoum dissociation constant was estimated to be 4.50. Log Pow was found to be 4.92 at pH 7 and 20°C. As expected, Log Pow decreased with higher temperature and pH.

Brodifacoum is not highly flammable. Besides, it does not show explosive or oxidising properties. Reaction with container materials (mild steel) has not been observed, either. All results considered, it can be concluded that Brodifacoum does not exhibit hazardous physical-chemical properties.

**2.3.1.3 Analytical method for determination of active ingredient and impurities in the technical active ingredient**

Analytical method for the determination of pure active substance brodifacoum in the technical active substance as manufactured has already been performed and validated at EU level in the CAR of brodifacoum (2010). The applicant TRIPLAN has a letter of access to these data.

**Summary: (source AR November 2010)**

	<b>Principle of method</b>
Technical active substance as manufactured:	Brodifacoum is analysed in the technical material by reversed-phased HPLC/UV (254nm) Purity : 96.2-99.4% w/w (mean: 98.1 % w/w)

**2.3.1.4 Analytical method for determining relevant components and/or residues in different matrices**

Analytical methods for the determination of residues of the active substance brodifacoum in the different matrices (plants, soil, drinking, ground, surface water, human and animal body fluids and tissues) have already been performed and validated at EU level in the CAR of brodifacoum (2010). No method in air is required since the active substance is non volatile.

Analytical methods are presented in Annex 3 of this document.

The applicant TRIPLAN has a letter of access to these data.

**2.3.2 Biocidal product**

**2.3.2.1 Identity, composition of the biocidal product, packaging**

The biocidal product is not the same as the one assessed for the inclusion of the active substance in annex I of directive 98/8/EC.

Trade name: *FANGA RAT-DICAL TECH*

Type of product: PT14, bait ready to use

Formulation type: grain bait

The composition of the product is confidential and is presented in a confidential annex. There is no substance of concern.

**2.3.2.2 Physico-chemical properties**

The tested product is FANGA RAT-DICAL TECH. Brodifacoum content in tested product is 0.0025% w/w. According to the declared content, it is in the range of the FAO tolerance (15%).

The product does not contain hydrocarbon compounds.

Table 1: Physico-chemical properties of the biocidal product (PAR 2015)

Subsection (Annex Point IIB. 3/TNsG)	Method	Purity/ Specification	Results <sup>3</sup>	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Evaluation FR
<b>3.1 Appearance (IIB3.1/Pt. I-B3.1)</b>		0.025 g/kg Brodifacoum						
<b>3.1.1 Physical state and nature</b>	Visual examination	FANGA RAT-DICAL TECH Batch 24/11	Crushed corn		Y	1	11-920010-029 <sup>4</sup>	Acceptable
<b>3.1.2 Colour</b>			Blue/ green crushed corn					
<b>3.1.3 Odour</b>	Not determinated			An odour should only be recorded if it is very apparent				
<b>3.2 Explosive properties (IIB3.2/Pt. I-B3.2)</b>	DSC internal method	0.025 g/kg Brodifacoum FANGA RAT-DICAL TECH Batch 24/11	During the first phase, one exothermic peak was observed at 246.7 °C with an enthalpy difference of 407.9 J/g which was lower than the limit of 500 J/g specified in the guideline. During the second phase, neither endothermic nor exothermic peak was observed up to 500 °C under the experimental conditions used. This thermodynamic information allows knowing that a test on explosive properties with EC A14 method should not be performed.		Y	1	11-920010-028 <sup>5</sup>	Acceptable. The product is not expected to have explosive properties.
	Literature survey on	0.025 g/kg Brodifacoum	According to the composition, the product does not contain compound classified as explosive. In addition, The DSC graph				11-920010-28	Acceptable. The product is not

<sup>3</sup> Give also data on test pressure, temperature, pH and concentration range if appropriate.

<sup>4</sup> Forand V. 2012. Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54±2°C on FANGA RAT-DICAL TECH in compliance with CIPAC MT 46.3 (CIPAC Handbook J – 2000). DEFITRACES, report n°11-920010-029 of 15 February 2012, GLP, unpublished.

<sup>5</sup> Colombies N. 2012. Physico chemical tests on FANGA RAT-DICAL TECH. DEFITRACES, report N° 11-920010-028 of 22 February 2012, GLP, unpublished.



**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

<b>Subsection (Annex Point IIB. 3/TNsG)</b>	<b>Method</b>	<b>Purity/ Specification</b>	<b>Results<sup>3</sup></b>	<b>Remarks/ Justification</b>	<b>GLP (Y/N)</b>	<b>Reli abili ty</b>	<b>Refere nce</b>	<b>Evaluation FR</b>
	explosive properties and oxidizing properties of the ingredients of the product FANGA RAT-DICAL TECH.	FANGA RAT-DICAL TECH Batch 24/11	shows an exothermic effect with decomposition energy lower than 500 J/g which confirms that the product FANGA RAT-DICAL TECH is not likely to be explosive.					expected to have explosive properties
<b>3.3 Oxidising properties (IIB3.3/Pt. I-B3.3)</b>	Literature survey on explosive properties and oxidizing properties of the ingredients of the product FANGA RAT-DICAL TECH.	0.025 g/kg Brodifacoum FANGA RAT-DICAL TECH Batch 24/11	Based on most recent approach of structural formulas, none of the ingredients has any potential for oxidizing properties. Accordingly, the product FANGA RAT-DICAL TECH is not expected to present a significant hazard, and testing is considered as unnecessary.			1	11-920010-028	Acceptable. The product is not expected to have oxidizing properties.
<b>3.4 Flash-point and other indications of flammability</b>	EC A10 method (2008)	0.025 g/kg Brodifacoum FANGA RAT-DICAL TECH Batch 24/11	<b>Preliminary test</b> Humidity about 40% Room temperature about 22 °C Atmospheric pressure 97.8 kPa <u>Assay No. 1</u> An incandescence of the test item was observed. After the removal of the burner's flame, the redness stopped after 2-3 seconds. Neither ignition nor propagation of the flame was observed. <u>Assay No. 2</u>		Y	1	11-920010-028	Acceptable. The product is not highly flammable.

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<b>Subsection (Annex Point IIB. 3/TNsG)</b>	<b>Method</b>	<b>Purity/ Specification</b>	<b>Results<sup>3</sup></b>	<b>Remarks/ Justification</b>	<b>GLP (Y/N)</b>	<b>Reli abili ty</b>	<b>Refere nce</b>	<b>Evaluation FR</b>
			The same observations as for the assay No. 1 were recorded. <b>Main test</b> Taking into account the results obtained during the preliminary test, no main test was performed.  The test item was not considered as highly flammable under the experimental conditions used.					
<b>Self ignition (IIB3.4/Pt. I-B3.4)</b>	<b>EC A16 method (2008)</b>	0.025 g/kg Brodifacoum FANGA RAT- DICAL TECH Batch 24/11	No self ignition of the test item was observed up to 400°C (corrected value)		Y	1	11- 920010 -028	Acceptable. The product is not auto-flammable
<b>3.5Acidity/Alkali nity (IIB3.5/Pt. I- B3.5)</b>	CIPAC MT 75.3	0.025 g/kg Brodifacoum FANGA RAT- DICAL TECH Batch 24/11	The pH mean value of the test item at 1% w/v in standard water D was: 5.84 at 21.2°C after 1 min. 5.85 at 21.3°C after 2 min.	The test item was not completely dissolved in standard water D.	Y	1	11- 920010 -029	Acceptable
<b>3.6 Bulk density (IIB3.6/Pt. I-B3.6)</b>	CIPAC MT 186 (2003)	0.025 g/kg Brodifacoum FANGA RAT- DICAL TECH Batch 24/11	The mean pour density of the test item was: 0.632 g/ml The mean tap density of the test item was: 0.700 g/ml		Y	1	11- 920010 -028	Acceptable
<b>3.7 Storage stability - stability and shelf</b>	<b>14 days at 54±2°C</b> CIPAC MT 46.3	0.025 g/kg Brodifacoum FANGA RAT- DICAL TECH Batch 24/11	<b>Test item: 25g plastic bags (PE) and white opaque plastic bucket</b>  <b>Aspect</b>		Y	1	11- 920010 -029	Acceptable. The product is stable in 25g PE bag.

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

Subsection (Annex Point IIB. 3/TNsG)	Method	Purity/ Specification	Results <sup>3</sup>	Remarks/ Justification	GLP (Y/N)	Reli abili ty	Refere nce	Evaluation FR
life (IIB3.7/Pt. I-B3.7)			<p>Before the accelerated storage procedure for 14 days at 54±2°C: Blue/green crushed corn in white opaque plastic bucket with white lid. Weight Bag: 1252.3 g.</p> <p>After the accelerated storage procedure for 14 days at 54±2°C: Blue/green crushed corn in white opaque plastic bucket with white lid. Weight Bag: 1251.0 g.</p> <p>DW= -0.1%</p> <p>The aspect of the test item was considered to be stable after an accelerated storage procedure for 14 days at 54 ±2 °C, no significant change of weight was observed. The packaging material was considered to be stable after an accelerated storage procedure for 14 days at 54 ±2 °C.</p>					
			<p><b>Analytical quantification of brodifacoum (analytical method validated in report n° 11-920010-015)</b></p> <p>Before the accelerated storage procedure for 14 days at 54±2°C the content of brodifacoum was:</p> <p>essay 1 (DEF 11-0607B): 0.0025% w/w. Essay 2 (DEF 11-0608): 0.0025%</p>					<p>Acceptable Variation of brodifacoum: -4%</p>

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

Subsection (Annex Point IIB. 3/TNsG)	Method	Purity/ Specification	Results <sup>3</sup>	Remarks/ Justification	GLP (Y/N)	Reli abili ty	Refere nce	Evaluation FR
			<p>After the accelerated storage procedure for 14 days at 54±2°C the content of brodifacoum was:</p> <p>essay 1 (DEF 11-0628): 0.0025% w/w. Essay 2 (DEF 11-0629): 0.0024%</p> <p>No significant change was observed in the content of brodifacoum in FANGA RAT-DICAL TECH (-4% deviation from T = 0 value) after the accelerated storage procedure for 14 days at 54 ±2 °C. The test item was considered to be stable</p>					
	CIPAC MT 75.3	0.025 g/kg Brodifacoum FANGA RAT- DICAL TECH Batch 24/11	<p><b>pH</b> Before the accelerated storage procedure for 14 days at 54±2°C: The pH mean value of the test item at 1% w/v in standard water D was: 5.84 at 21.2°C after 1 min. 5.85 at 21.3°C after 2 min. After the accelerated storage procedure for 14 days at 54±2°C: The pH mean value of the test item at 1% w/v in standard water D was: 5.61 at 21.3°C after 1 min. 5.63 at 21.3°C after 2 min.</p>		Y	1	11- 920010 -029	Acceptable
	CIPAC 58.3	0.025 g/kg Brodifacoum FANGA RAT- DICAL TECH Batch 24/11	<p><b>Dust content</b> Before the accelerated storage procedure for 14 days at 54±2°C: 0.52% w/w (passing through a 150µm sieve) and 1.22% w/w (retained of a 150µm sieve)</p>		Y	1	11- 920010 -029	Acceptable

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Subsection (Annex Point IIB. 3/TNsG)	Method	Purity/ Specification	Results <sup>3</sup>	Remarks/ Justification	GLP (Y/N)	Reli abili ty	Refere nce	Evaluation FR
			<p>The dust content of the test item was 0.52% (w/w)</p> <p>After the accelerated storage procedure for 14 days at 54±2°C: 0.14% w/w (passing through a 150µm sieve) and 0.24% w/w (retained of a 150µm sieve) The dust content of the test item was 0.14% (w/w)</p>					
	CIPAC MT 46.3	0.025 g/kg Brodifacoum FANGA RAT-DICAL TECH Batch 24/11	<p><b>Test item: polyethylene bags</b></p> <p><b>Aspect and packaging</b> Before the accelerated storage procedure for 14 days at 54±2°C: Blue green crushed corn Plastic bag Weight: Wbag 10: 115.1 g Wbag 12: 108.5 g Wbag 13: 112.3 g</p> <p>After the accelerated storage procedure for 14 days at 54±2°C: Blue green crushed corn Plastic bags Weights: Wbag 10: 109.4 g Wbag 12: 103.1 g</p>		Y	1	12-920010-011 <sup>6</sup>	Acceptable. PE bags are stable after accelerated storage

<sup>6</sup> Grevin P. 2012. Physico chemical tests before and after an accelerated storage procedure for 14 days at 54 ± 2°C on FANGA RAT-DICAL TECH. DEFITRACES, Report 12-920010-011 of 27 September 2012, GLP, unpublished.

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Subsection (Annex Point IIB. 3/TNsG)	Method	Purity/ Specification	Results <sup>3</sup>	Remarks/ Justification	GLP (Y/N)	Reli abili ty	Refere nce	Evaluation FR												
			<p>Wbag 13: 106.9 g</p> <p>Difference of weight: DWbag 10 = -5.0% DWbag 12 = -5.0% DWbag 13 = -4.8%</p> <p>The aspect of the test item was considered to be stable after an accelerated storage procedure for 14 days at 54 ± 2 °C, no significant change of weight was observed. The packaging material was considered to be stable after an accelerated storage procedure for 14 days at 54 ± 2 °C.</p>																	
	MT 59.4 method (1995)		<p><b>Sieve test for granular materials</b></p> <p>Before the accelerated storage procedure for 14 days at 54±2°C: 0.2% of the residue was retained by the 125-µm sieve and 0.5% was collected in the collecting pan.</p> <table border="1" data-bbox="810 1074 1072 1361"> <thead> <tr> <th>Test sieves</th> <th>% of residue</th> </tr> </thead> <tbody> <tr> <td>5.6 mm</td> <td>2.5</td> </tr> <tr> <td>4.0mm</td> <td>17.5</td> </tr> <tr> <td>2.8mm</td> <td>61.2</td> </tr> <tr> <td>2.0mm</td> <td>13.4</td> </tr> <tr> <td>Collecting pan</td> <td>5.3</td> </tr> </tbody> </table>	Test sieves	% of residue	5.6 mm	2.5	4.0mm	17.5	2.8mm	61.2	2.0mm	13.4	Collecting pan	5.3		Y		12- 920010 -011	Acceptable.
Test sieves	% of residue																			
5.6 mm	2.5																			
4.0mm	17.5																			
2.8mm	61.2																			
2.0mm	13.4																			
Collecting pan	5.3																			

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

Subsection (Annex Point IIB. 3/TNsG)	Method	Purity/ Specification	Results <sup>3</sup>	Remarks/ Justification	GLP (Y/N)	Reli abili ty	Refere nce	Evaluation FR												
			<p>The major part of the test item (61.2%) was situated between 2.8 mm and 4.0 mm.</p> <p>After the accelerated storage procedure for 14 days at 54±2°C: 0.6% of the residue was retained by the 125-µm sieve and 0.7% was collected in the collecting pan.</p> <table border="1" data-bbox="810 612 1072 900"> <thead> <tr> <th>Test sieves</th> <th>% of residue</th> </tr> </thead> <tbody> <tr> <td>5.6 mm</td> <td>2.2</td> </tr> <tr> <td>4.0mm</td> <td>13.7</td> </tr> <tr> <td>2.8mm</td> <td>58.8</td> </tr> <tr> <td>2.0mm</td> <td>18.5</td> </tr> <tr> <td>Collecti ng pan</td> <td>6.7</td> </tr> </tbody> </table> <p>The major part of the test item (58.8%) was situated between 2.8 mm and 4.0 mm.</p>	Test sieves	% of residue	5.6 mm	2.2	4.0mm	13.7	2.8mm	58.8	2.0mm	18.5	Collecti ng pan	6.7					
Test sieves	% of residue																			
5.6 mm	2.2																			
4.0mm	13.7																			
2.8mm	58.8																			
2.0mm	18.5																			
Collecti ng pan	6.7																			
	MT 171 method (1995)		<p><b>Dustiness</b> Before the accelerated storage procedure for 14 days at 54±2°C: Gravimetric collected dust: 5.6-8.3mg (2essays) The category of the test item was 1 (nearly dust-free).</p> <p>After the accelerated storage procedure for 14 days at 54±2°C: Gravimetric collected dust: 4.4-5.2mg (2essays)</p>		Y		12- 920010 -011	<p>Acceptable. The product is nearly dust free.</p> <p>Friability was not provided after accelerated storage and is required in post registration.</p>												

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

<b>Subsection (Annex Point IIB. 3/TNsG)</b>	<b>Method</b>	<b>Purity/ Specification</b>	<b>Results<sup>3</sup></b>	<b>Remarks/ Justification</b>	<b>GLP (Y/N)</b>	<b>Reli abili ty</b>	<b>Refere nce</b>	<b>Evaluation FR</b>
			The category of the test item was 1 (nearly dust-free).					
Effect of light								No data has been provided.
Effect of low temperature								No data provided. Not required since the product is a solid.
Shelf life								No result has been provided. (test started on October 2011)
<b>3.8 Technical characteristics (IIB3.8/Pt. I-B3.8)</b>								
Wettability/ Suspensibility				Only solid preparations				Not applicable
Wet sieve analysis				For WPs, SCs, granules, tablets				Not applicable
Emulsifiability				Only for ECs and ready for use emulsions				Not applicable
Disintegration time				Only for tablets				Not applicable
friability of granules; integrity of tablets	CIPAC MT 178 (1998)	0.025 g/kg Brodifacoum	The friability of the test item was: 99.8% (rounded to the nearest 0.1%).		Y	1	11-920010-028	Acceptable (limit accepted: 98%)



**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

<b>Subsection (Annex Point IIB. 3/TNsG)</b>	<b>Method</b>	<b>Purity/ Specification</b>	<b>Results<sup>3</sup></b>	<b>Remarks/ Justification</b>	<b>GLP (Y/N)</b>	<b>Reli abili ty</b>	<b>Refere nce</b>	<b>Evaluation FR</b>
		FANGA RAT-DICAL TECH Batch 24/11						
Persistence of foaming								Not applicable
Flowability	CIPAC MT 172 method (1995)	0.025 g/kg Brodifacoum FANGA RAT-DICAL TECH Batch 24/11	Mass of the test item: 50g The test item did not dropped spontaneously through the 5-mm sieve. The mean percentage of test item retained on the 5-mm sieve after 5 liftings was: 11.7 ± 0.9% w/w. The mean percentage of test item retained on the 5-mm sieve after 20 liftings was: 3.9 ± 0.1% w/w.		Y	1	12-920010-011	The test item did not flow spontaneously through the 5mm sieve. As the product is not sold loose, flowability is not required.
Dust content	CIPAC MT 58.3	0.025 g/kg Brodifacoum FANGA RAT-DICAL TECH Batch 24/11	0.52% w/w (passing though a 150µm sieve) and 1.22% w/w (retained of a 150µm sieve) The dust content of the test item was 0.52% (w/w)		Y	1	11-920010-029	Acceptable
Dustiness	CIPAC MT 171 (1995)	0.025 g/kg Brodifacoum FANGA RAT-DICAL TECH Batch 24/11	Before the accelerated storage procedure for 14 days at 54±2°C: Gravimetric collected dust: 5.6-8.3mg (2essays) The category of the test item was 1 (nearly dust-free).		Y	1	12-920010-011	Acceptable. The product is nearly dust free.
<b>3.9Compatibility with other products (IIB3.9/Pt. I-B3.9)</b>								Not applicable

Subsection (Annex Point IIB. 3/TNsG)	Method	Purity/ Specification	Results <sup>3</sup>	Remarks/ Justification	GLP (Y/N)	Reli abili ty	Refere nce	Evaluation FR												
3.10 Surface tension (Pt. I- B3.10)								Not applicable												
3.11 Viscosity (Pt. I- B3.10)								Not applicable												
3.12 Particle size distribution (Pt. I-B3.11)	MT 59.4 method (1995)	0.025 g/kg Brodifacoum FANGA RAT- DICAL TECH Batch 24/11	<p>Before the accelerated storage procedure for 14 days at 54±2°C: 0.2% of the residue was retained by the 125-µm sieve and 0.5% was collected in the collecting pan.</p> <table border="1"> <thead> <tr> <th>Test sieves</th> <th>% of residue</th> </tr> </thead> <tbody> <tr> <td>5.6 mm</td> <td>2.5</td> </tr> <tr> <td>4.0mm</td> <td>17.5</td> </tr> <tr> <td>2.8mm</td> <td>61.2</td> </tr> <tr> <td>2.0mm</td> <td>13.4</td> </tr> <tr> <td>Collecting pan</td> <td>5.3</td> </tr> </tbody> </table> <p>The major part of the test item (61.2%) was situated between 2.8 mm and 4.0 mm. The major part of the test item (61.2%) was situated between 2.8 mm and 4.0 mm.</p>	Test sieves	% of residue	5.6 mm	2.5	4.0mm	17.5	2.8mm	61.2	2.0mm	13.4	Collecting pan	5.3		Y	1	12- 920010 -011	Acceptable
Test sieves	% of residue																			
5.6 mm	2.5																			
4.0mm	17.5																			
2.8mm	61.2																			
2.0mm	13.4																			
Collecting pan	5.3																			

**Conclusion (PAR 2015):**

The product FANGA RAT-DICAL TECH is a ready to use grain bait for mice and rats. The product is not flammable and not auto-flammable (temperature of auto-flammability above 400°C). It has no explosive or oxidizing properties. The pH of the product at 1%w/v in water after 2 min at 21.3°C is 5.85. The density of the product is 0.632g/mL and the tap density is 0.700g/mL. The friability of the product is 99.8%. The product is nearly dust free, as less than 10mg of dust was determined with the gravimetric method. The flowability of the product has not been demonstrated since 3.9% of the test item (50g) is still retained on a 5mm sieve after 20 liftings. As the product is not sold loose, this deviation is not critical.

After storage at 54°C for 14 days in 25g PE bags, the content of active substance decreased up to 4%. No effect of the temperature on the chemical properties of the product has been observed. Friability was not provided after accelerated storage and is required post-registration according to CIPAC MT 178.

No result has been provided for the long term stability (end of the study: November 2013). As the accelerated storage is acceptable, a shelf life of 2 years can be granted. Study is required post registration to confirm the shelf life of the product.

**Data requirement:**

Friability was not provided after accelerated storage and is required post-registration according to CIPAC MT 178.

The long term storage stability study is also required post-registration.

➤ **Major change and post-authorisation - 2016**

The following data were requested post-authorization and submitted and evaluated in 2016

- Results of the shelf life study 2 years at ambient temperature.
- Results of the attrition resistance after accelerated storage stability

Physico-chemical properties of the biocidal product (PAR 2016).

(Sub)Section (Annex point)	Method	Purity/ specifications	Results	Reference	FR evaluation
<b>B3.7 Storage stability</b>					
<b>2 years at ambient temperature</b>	CIPAC MT 75.3  Technical monograph n°17, 2 <sup>nd</sup> edition, 2009	FANGA RAT-DICAL TECH Batch 24/11	<p>The pH mean value of the test item at 1% m/v in standard water D is :</p> <p>5.84 at 21.2 °C after 1 min. 5.85 at 21.3°C after 2 min.</p> <p>The pH of the test item being higher than 4 and lower than 10, the test CIPAC MT 191 was not performed.</p> <p>After 24 months of storage procedure at 20 ± 2°C The mean pH value of the test item at 1% w/v in standard water D was: 5.91 at 20.9 °C after 1 min. 5.89 at 20.9 °C after 2 min.</p> <p><b>Aspect:</b> <i>Before storage</i> Heterogeneous blue /green crushed corn <i>After</i> the procedure of storage for 6 months: No modification of appearance. <i>After</i> the procedure of storage for 12 months: No modification of appearance. <i>After</i> the procedure of storage for 2 years: No modification of appearance.</p> <p><b>Appearance and stability of the commercial type package</b> <i>Before storage</i> Transparent polyethylene bags and Paper and PE bag with 2 layers of paper and one layer of polyethylene inside Bag 4: Mass (product + packaging) = 57.2 g Bag 5: Mass (product + packaging) = 55.8 g</p>	11-920010-030 <sup>7</sup>	<p>Acceptable</p> <p>Acceptable.</p> <p>Acceptable. The product is compatible with paper/PE bags and therefore with all claimed packaging since it is a solid.</p>

<sup>7</sup> Demangel B. 2014. Physico-chemical tests and chemical stability after a storage procedure for 2 years at 20 ± 2 °C on FANGA RAT-DICAL TECH In compliance with Technical Monograph No. 17, 2nd edition CropLife International. DEFITRACES, Report n° 11-920010-030 of 29 January 2014, GLP

		<p>Bag 6: Mass (product + packaging) = 53.0 g          Bag 7: Mass (product + packaging) = 62.3 g          Paper and PE bag with 2 layers of paper and one layer of polyethylene inside 14: 1906.7 g</p> <p><u>After</u> the procedure of storage for <u>6 months</u>:          No change in the appearance of the packaging.          Bag 4: Mass (product + packaging): 55.2 g          Difference : -3.5%          Bag 5: Mass (product + packaging): 53.9 g.          Difference : -3.4%</p> <p><u>After</u> the procedure of storage for <u>12 months</u>:          No change in the appearance of the packaging.          Bag 6: Mass (product + packaging): 51.7 g          Difference : -2.5%          Bag 7: Mass (product + packaging): 60.6 g.          Difference : -2.7%</p> <p><u>After</u> the procedure of storage for <u>2 years</u>:          No change in the appearance of the packaging.          Multilayers Paper/PE bags: Mass at sampling (product + packaging): 1855.9 g.          Difference : <b>-2.7%</b></p> <p>According to the formula: <math>DW = [(WT - W0) / W0] \times 100</math>          where DW is the difference of weight in %.          WT is the final mass of the packaging at the specified time.          W0 is the initial mass of the packaging.</p>		
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	<p>HPLC Defitraces Report n°11- 920010-031 and n°11- 920010-015 AMD (analytical method validated)</p> <p>MT 171 (1995)</p> <p>MT 59.4 (1995)</p> <p>MT 58.3 1995</p>		<p><b>Quantitative analysis of Brodifacoum</b> Initial active substance content: 0.0025% w/w <u>After</u> the procedure of storage for 6 months: Active substance content: 0.0026% w/w Deviation from the T = 0 value: +4.0% <u>After</u> the procedure of storage for 12 months: Active substance content: 0.0024% w/w Deviation from the T = 0 value: -4.0% <u>After</u> the procedure of storage for 2 years: Active substance content: 0.0022% w/w Deviation from the T = 0 value: <b>-12.0%</b></p> <p><b>Dustiness</b> Before storage: the test was not performed. After 24 months: 7mg</p> <p><b>Dry sieve test</b> Before storage: 0.2% of the residue was retained by the 125-µm sieve and 0.5% was collected in the collecting pan. The major part of the test item (61.2%) was situated between 2.8 mm and 4.0 mm. After 24months: the test item contains 0.5% of dust. The major part (63.5%) was situated between 2.8 and 4.0mm.</p> <p><b>Size of dust</b> Before storage: the cumulative percentage by mass (including loss during sieving) of the sample passing through the 250 µm was 1.2% w/w. After 24 months: the cumulative percentage by mass (including loss during sieving) of the sample passing through the 250-µm sieve was lower than 0.1% w/w.</p>	<p>Acceptable. Variations after 2 years are above 10%. Nevertheless, intermediate results were provided (6 months and 12months), and it has been demonstrated that the decrease is not linear. It can be assumed that variations are due to the heterogeneity of the product.</p> <p>The product is nearly dust free. Test was performed before storage in the accelerated storage study and the product was also nearly dust free.</p>
<p><b>B3.8 Technical characteristics (IIB3.8/Pt. I-B3.8)</b></p>				
			<p><b>Attrition resistance</b> No results were provided.</p>	<p>Acceptable. Since results after</p>

	CIPAC MT 59.4		<b>Particle size distribution after storage</b> Test sieve: 5.6mm: 3.4% 4.0mm: 15.8% 2.8mm: 63.5% 2.0mm: 13.9% Collecting pan: 2.9%		accelerated storage are acceptable, no further data are required.  Acceptable
<b>Attrition resistance</b>	CIPAC MT178	BDM25V1, batch 03/15	Before the accelerated storage procedure during 14 days at 54°C ± 2°C: The attrition resistance of the test item was 99.6% After the accelerated storage procedure during 14 days at 54°C ± 2°C: The attrition resistance of the test item was 100%	15-920010-010 <sup>8</sup>	Acceptable.

<sup>8</sup> Demangel B. Attrition resistance of granules test before and after an accelerated storage procedure at 54 °C ± 2 °C for 14 days on BDM25V1 In compliance with CIPAC Handbook J - MT 46.3 method (2000). Défitraces, rapport n° 15-920010-010 of 29 April 2015, GLP.



➤ **Renewal application - 2017:**

No change has been claimed.

**General conclusion on the physical, chemical and technical properties of the product for renewal of national authorisation applications**

The product FANGA RAT-DICAL TECH is a ready to use grain bait formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidising properties. The product is not flammable.

The appearance of the product is heterogeneous blue /green crushed corn and with no specific odor. Storage stability study results are acceptable. The biocidal product is stable 2 weeks at 54°C and 2 years at ambient temperature with multilayers Paper/PE bags. Considering that the product is a solid and it is compatible with multilayers Paper/PE bags, compatibility with other claimed packagings is considered acceptable.

eCA recommends to store away from light due to the sensitivity of the active substance to light.

It's technical characteristics are acceptable for a ready to use grain bait formulation.

➤ **Minor change application (FANGA 5 CEREALES 25)- 2022**

A stability long-term storage is on-going and it should be provided when available.

A mitigation measure should be added on the label : store the product at temperature below 40°C.

Subsection (Annex Point IIB. 3/TNsG)	Method	Purity/ Specification	Results <sup>9</sup>	Reference	Evaluation FR										
<b>Appearance</b> <b>pH value</b> <b>relative density</b> <b>Dustiness</b>	OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304 CIPAC MT 75.3; EC 440/2008 No. A.3 CIPAC MT 171.1	<b>Test item:</b> BDCE25V1 Batch n°: 05170619FR0 7CM25	<table border="1"> <thead> <tr> <th data-bbox="860 331 1249 363">Test</th> <th data-bbox="1249 331 1653 363">Results</th> </tr> </thead> <tbody> <tr> <td data-bbox="860 363 1249 491">Appearance (Colour, odour and physical state)</td> <td data-bbox="1249 363 1653 491">Blue green (shortcode BLG 6) solid (grain) with characteristic odour</td> </tr> <tr> <td data-bbox="860 491 1249 555">pH value (1% aqueous dilution) (1)</td> <td data-bbox="1249 491 1653 555">8.0</td> </tr> <tr> <td data-bbox="860 555 1249 587">Relative Density</td> <td data-bbox="1249 555 1653 587">1.2878 g/mL at 20°C</td> </tr> <tr> <td data-bbox="860 587 1249 683">Dustiness of granular products - Gravimetric Method</td> <td data-bbox="1249 587 1653 683">(nearly dust 1.2 mg-free)</td> </tr> </tbody> </table>	Test	Results	Appearance (Colour, odour and physical state)	Blue green (shortcode BLG 6) solid (grain) with characteristic odour	pH value (1% aqueous dilution) (1)	8.0	Relative Density	1.2878 g/mL at 20°C	Dustiness of granular products - Gravimetric Method	(nearly dust 1.2 mg-free)	CH-0737- 2019 Nichetti N. 2019	Acceptable <b>But bulk density should                      have been provided.</b>
Test	Results														
Appearance (Colour, odour and physical state)	Blue green (shortcode BLG 6) solid (grain) with characteristic odour														
pH value (1% aqueous dilution) (1)	8.0														
Relative Density	1.2878 g/mL at 20°C														
Dustiness of granular products - Gravimetric Method	(nearly dust 1.2 mg-free)														

<sup>9</sup> Give also data on test pressure, temperature, pH and concentration range if appropriate.

<b>Accelerated storage</b>	Analytical method : No. 0738/2019 validated below OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304 CIPAC MT 75.3; EC No 440/2008 A.3 CIPAC MT 171.1	<b>Test item:</b> BDCE25V1 Batch n°: 05170619FR0 7CM25: new composition	<b>Test</b>	<b>Initial characterisation</b>	<b>After 8 weeks at 40°C</b>	CH-0739-2019 Nichetti N. 2019	The nature of the packaging should have been provided. The product can be considered as stable at 40°C.
			Packaging	Plastic sachet	Plastic sachets, labelled "A1", "A2", "B1" and "B2"		
			Weight variation (%)	-	A1: -1.86%; A2: -1.08%; B1: -1.61%; B2: -2.11%		
			Appearance (1) (Colour, odour and physical state)	Blue green (shortcode BLG 6) solid (grain) with characteristic odour	Blue green (shortcode BLG 6) solid (grain) with characteristic odour		
			Brodifacoum active ingredient content	0.0029 ± 0.00004 % w/w	0.0028 ± 0.00002 % w/w		
			Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)	-	The sachet didn't present any deformation or loss of sample and evident corrosion phenomena		
			pH value (2) (1% aqueous dilution)	8.0	6.9		
			Relative density	1.2878 g/mL at 20°C	1.2832 g/mL at 20°C		
			Dustiness	1.2 mg (nearly dust-free)	1.4 mg (nearly dust-free)		

<p><b>Bulk density</b></p>	<p>CIPAC MT 186</p>	<p><b>Test item:</b> BDCE25V1</p>	<p>Pour density: 0.67 g/mL Tap density: 0.71 g/mL</p>	<p>CHE-OR-21-20469 Nichetti S. 2022</p>	<p>Results are similar to the first composition. There is a difference and an inconsistency between the bulk density and the relative density, but this data does not affect the minor change.</p>
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**Conclusion:**

Accelerated storage stability and additional characteristics of the new composition of the product were provided and show that the new composition is stable at temperature below 40°C and have the similar physical chemical characteristics.

The ongoing long-term stability storage should be provided in the frame of the renewal of the product.

**2.3.3 Analytical methods for detection and identification**

**2.3.3.1 Analytical method for determining the active substance and relevant component in the biocidal product**

Analytical method for the determination of brodifacoum in the product has been provided.

Principle of the method: brodifacoum is analyzed after extraction from the product with methanol, filtered and quantified by reverse phase HPLC-UV.

Chromatographic conditions:

Colum: Zorbax SB Phenyl, length: 25cm, internal diameter: 3.0mm, granulometry: 5.0µm, Agilent.

Detector: UV, 265nm.

Mobile phase: Eluent A acetonitrile, Eluent B water/acetic acid 34/1.

Time (min)	Eluent% A	Eluent %B	Rate (mL/min)
0	70	30	1.0
15	70	30	1.0

Rate: 1(mL/min).

Oven temperature: 30°C.

Volume injected: 20µL.

Retention times (min): 4.9 for brodifacoum I and 5.4 for brodifacoum II.

Linearity was performed with 5 calibration standards, prepared in methanol, from 0.51 to 1.50mg/L. The same linearity was used for the determination of active substance in the product FANGA RAT-DICAL TECH and FANGA BLOC SP PRO.

Precision was performed by analyzing twice five samples of FANGA BLOC SP PRO. The extraction is the same as for FANGA RAT-DICAL TECH.

Specificity and accuracy were performed with the formulation FANGA RAT-DICAL TECH:

Test item: FANGA RAT-DICAL TECH, Batch 24/11.

Blank formulation: (FANGA RAT-DICAL TECH): Batch 29/11.

Reference item: brodifacoum, purity 99.3%, batch SZB8324XV (supplier: SIGMA Aldrich).

Results are summarized in the following table.

Table 2: Analytical method for the determination of brodifacoum (reverse phase HPLC-UV)

Sample	Test substance	Analytical method	Fortification range/ number of measurements	Linearity	Specificity	Recovery rate (%)			Repeatability	Reference
						range	Mean	St dev.		
FANGA RAT DICAL TECH Batch 24/11/01  Blank formulation Batch 29/11	brodifacoum	reverse phase HPLC- UV	Fortification levels: reconstituted sample at 1 concentration level (0.0025%, 1mg/L in solution after dilution)  Two samples prepared and analysed in duplicate	0.51- 1.50mg/L  Y= 1.4717x -0.09  R <sup>2</sup> =0.9965	No interference observed in solvent blank and formulation blank	99-100%  Two reconstituted samples in duplicate at 0.0025% (1mg/L)	99.7 5%	SD: 0.5  RSD: 0.5%	5 samples (FANGA BLOC PRO) in duplicate  Mean: 0.0045% (w/w) SD:0.0001 RSD: 2.90%  Horwitz value: 6.04	RICAU hélène, report No. 11- 920010-015, May 2012  RICAU Hélène, report No. 11- 920010-031, February 2012

Chromatograms were provided for the formulation blank, reference item and test item (at 0.0025% w/w of active substance). No interference has been observed at the retention time of brodifacoum. Specificity of the method is acceptable.

Linearity has been demonstrated with 5 calibration standards.

According to Sanco/3030/99 rev.4, recoveries should be between 80-120% for active substances with nominal content below 0.01%. Accuracy is acceptable.

RSD is below Horwitz value. Repeatability is acceptable.

It is concluded that the provided method is validated and acceptable for the product FANGA RAT-DICAL TECH.

➤ **Minor change application (FANGA 5 CEREALES 25)- 2021**

BDCE25V1: Analytical Method for the Determination of the Active Ingredient Content; Nichetti ; 2019

Test facility: ChemService S.r.l. Controlli e Ricerche, GLP Studies Department, Via F.lli Beltrami, 15; 20026 Novate Milanese - MI - (Italy)

Principle of the method:

Using the technical balance, about 20 g of the test item were weighed into a 250 mL conical flask, then 100.00 mL of diluting mixture were added and the flask was placed in an ultrasonic bath for 30 minutes, then onto a magnetic stirrer for 24 hours. That time elapsed, an aliquot was filtered using a 0.45 µm syringe filter into a vial for the HPLC analysis. Brodifacoum is analysed by HPLC-UV at 270nm by external standard calibration.

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

Validation data:

Specificity	To demonstrate the specificity of the method, several solution are analyzed: <ul style="list-style-type: none"> <li>- Solvent wash</li> <li>- blank Formulation</li> <li>- Reference item of the active substance std</li> <li>- Test item of the product</li> <li>- Fortified formulation</li> </ul> No interference was found: no peak appears in the solvent blank and in the formulation blank, one peak is observed at the same retention time for the reference item and test item. All chromatograms were available.	
Linearity	Linearity was studied by carrying out five concentrations between 0.0010-0.0040 % w/w of the reference item (n=1). Calibration curve has been provided with a R <sup>2</sup> higher than 0.99.	
	Compound	Linearity
	Active substance	0.0010-0.0040 % w/w Y = 556444x + 12559 R <sup>2</sup> = 0.99 n=1 5 levels
Precision	Repeatability was evaluated by analyzing five test item solutions.	
	Compound	Repeatability (RSD)
	AS at 0.0025%w/w	RSD = 1.40%



Accuracy	Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.			
	Fortification level	recovery rate	Mean recovery rate	n
	100%: 0.0025%	100.13%	100.3%	1
	100%: 0.0025%	100.48%		1

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

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

The analytical methods for determination of residues of active substance in different matrices (soil, air, drinking and surface water, body fluids and tissues, in food and feedstuff) provided in the CAR of the active substance are presented in annex 3 of this document.

Since there is no risk of contact with alimentation, no analytical method is required for the determination of brodifacoum residues in food and feedstuff.

## 2.4 Risk assessment for Physico-chemical properties

FANGA RAT-DICAL TECH is not flammable, not auto-flammable (up to 400°C), not explosive and does not have oxidizing properties according to GHS guideline. FR considers these conclusions are still valid for CLP classification as no formulant is expected to be classified for physico-chemical CLP properties.

### ➤ Major change application / post-authorization data – 2016

Based on the new data, product FANGA RAT DICAL TECH was considered to be stable after 24 months of storage procedure at 20 °C ± 2 °C, The packaging material (paper/PE) was considered to be stable after 24 months of storage procedure at 20 °C ± 2 °C.

The product is compatible with all new claimed packaging as biocidal product is a solid. No further data are required.

## 2.5 Effectiveness against target organisms

### 2.5.1 Function

MG 03: Pest Control.

Product Type 14: Rodenticide.

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

According to the uses claimed by the applicant, the product FANGA RAT-DICAL TECH is intended to be used to control rats and mice. The target organisms to be controlled are *Mus musculus*, *Rattus norvegicus* and *Rattus rattus*.

FANGA RAT-DICAL TECH is used indoor by professional users. The products, organisms or objects to be protected are public and private buildings, and farms.

The application rates recommended by the applicant are the following (see also Annex 0a):

Rats : 180 - 200 g grains/secured bait point separated by 5-10 m.

Mice : 50 g grains/secured bait point separated by 1-2 m.

### ➤ Major change and post-authorisation - 2016

The new application rates claimed by the applicant are the following:

In and around buildings, open areas and waste dumps and landfills

- Rats: 200 g per baiting point separated by 5 -10 m.
- Mice: 40 g per baiting point separated by 1 - 2 m.

New efficacy data have been submitted and assessed in the section below.

### 2.5.3 Effect on target organisms and efficacy

Brodifacoum is a second-generation single dose anticoagulant which prevents blood clotting in the target.

Clinical signs are progressive and occur three days after the ingestion of a toxic dose, leading to the death of target animal within 7 to 11 days after, according to the laboratory tests performed.

- For the first authorization, the applicant submitted the following studies:
  - Study n°: ROD 2012 06: laboratory study:

For brown rats (*Rattus norvegicus*), the overestimated mean palatability percentage is 2.9 % (recalculated to 1 %) and the mortality percentage of 20%.

For house mice (*Mus musculus*): the overestimated mean palatability percentage is 20.1 % (recalculated to 17.5 %) and the mortality percentage of 70 %.

Considering the results obtained in these trials, efficacy of the product FANGA RAT-DICAL TECH is not proved. Following the applicant consultation, new efficacy and palatability laboratory studies and a field study, reported below, have been performed to complete the efficacy of the dossier.

- Study n° 12 TOX024-13: laboratory study

For brown rats (*Rattus norvegicus*), the mean palatability percentage was 29 % and the mortality percentage was 100%. Death occurs between day 5 to day 10.

- Study n° 12 TOX024-9: laboratory study

For house mice (*Mus musculus*), the mean palatability percentage was 28 % and the mortality percentage was 100 %. Death occurs between day 7 to day 11.

- Study n°12 TOX24-16: field study

For house mice (*Mus musculus*), the test was conducted in a small farm. The assessed bait has been very well accepted and the efficacy was estimated at 100 %.

French competent authorities (FR CA) consider that the elements presented in the dossier are sufficient to demonstrate the efficacy of the product against mice (*Mus musculus*) but not against rats. Indeed according to the the Technical Notes for Guidance on product evaluation, Appendices to chapter 7 product TP14<sup>10</sup>, and according to the results of an european consultation, additionally to the laboratory tests, field tests have to be performed to confirm the efficacy of the product against the claimed target organisms.

Furthremore, FR CA consider that for the claim "use against rats", efficacy must be shown on both species *R. norvegicus* and *R. rattus*.

Then the French competent authorities consider that only the efficacy of the product FANGA RAT-DICAL TECH against house mice (*Mus musculus*) is demonstrated.

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<sup>10</sup> Technical Notes for guidance on product evaluation appendices to Chapter 7 Product Type 14 Efficacy Evaluation of Rodenticidal Biocidal Products.

All efficacy studies are presented in annex 9.

➤ **Major change application and post authorisation requirements – 2016**

New efficacy studies were conducted with FANGA RAT-DICAL TECH, on *Rattus norvegicus*, *Rattus rattus* and *Mus musculus*, with aged and fresh bait, to confirm the efficacy of the biocidal product for this species.

➤ Study n° 15TOX006, laboratory study with fresh bait:

For brown rats (*Rattus norvegicus*), the mean palatability percentage of **FANGA RAT-DICAL TECH** (0.0025 % brodifacoum Maize bait) was 35 % and the mortality percentage was 90 %.

Study n° 15TOX007, laboratory study with fresh bait:

For black rats (*Rattus rattus*), the mean palatability percentage of **FANGA RAT-DICAL TECH** (0.0025 % brodifacoum Maize bait) was 40 % and the mortality percentage was 90 %.

➤ Study n°2007.BCD.SAG15, field study with aged bait

For house mice (*Mus musculus*), **FANGA RAT-DICAL TECH** (0.0025 % brodifacoum Maize bait) aged more than 2 years showed a high acceptance level and efficacy was estimated at 100 % against the population present across the trial site.

➤ Study n°2005.BCD.SAG15, field study with aged bait

For brown rats (*Rattus norvegicus*), **FANGA RAT-DICAL TECH** (0.0025 % brodifacoum Maize bait) aged more than 2 years showed a high acceptance level and efficacy was estimated at 100 % against the population present across the trial site.

➤ Study n°2006.BCD.SAG15, field study with aged bait

For black rats (*Rattus rattus*), **FANGA RAT-DICAL TECH** (0.0025 % brodifacoum Maize bait) aged more than 2 years showed a high acceptance level and efficacy was estimated at 100 % against the population present across the trial site.

➤ Study n°2010.BCD.SAG13, field study with fresh bait:

For black rats (*Rattus rattus*), **FANGA RAT-DICAL TECH** showed a high acceptance level and efficacy was estimated at 100 % against the population present across the trial site.

French competent authorities (FR CA) consider that the elements presented in the dossier are sufficient to demonstrate the efficacy of the product FANGA RAT-DICAL TECH against *Rattus norvegicus*, *Rattus rattus* and *Mus musculus*. Furthermore, the studies performed with 2 year aged baits confirmed that the product remains effective 2 years after production.

For the use in sewers, FR CA considers that the grain form is not appropriate for the use in sewers: Indeed the conditions of use in sewers can damage the product, or the grains can disperse in the environment by stream of water or by animals.

All efficacy studies are presented in annex 9bis.

➤ **Renewal application - 2017:**

For the renewal of the product **FANGA RAT-DICAL TECH** (0.0025 % w/w brodifacoum), no change in the composition has been declared. The efficacy evaluation is based on the efficacy studies submitted by the applicant for the major application change and post-authorisation requirements.

Consequently, the product FANGA RAT-DICAL TECH (0.0025 % w/w brodifacoum) has shown a sufficient efficacy and can be used for the control of rats (*Rattus norvegicus* and *Rattus rattus*) and house mice (*Mus musculus*) at doses claimed.

Uses and doses validated for FANGA RAT-DICAL TECH are the following:

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

➤ **Minor change application (FANGA RAT-DICAL TECH) 2018**

The product **FANGA RAT-DICAL TECH**, containing 0.0025 % w/w brodifacoum, was renewed for use against *Mus musculus*, *Rattus norvegicus* and *Rattus rattus*, in and around buildings and outdoor environments (open areas and waste dumps) by professional users and in buildings against *Mus musculus* and in and around buildings against *Rattus norvegicus* and *Rattus rattus* by non-professional users, with a shelf-life of 24 months.

The validated application rates were the following:

- Rats (*Rattus norvegicus*, *Rattus rattus*): 200 g of bait/secured bait point separated by 5-10 m.
- Mice (*Mus musculus*): 40 g of bait/secured bait point separated by 1-2 m.

The new application rates for the same uses claimed by the applicant are the following:

- Rats: 100 g of bait /secured bait point separated by 5-10 m.
- Mice: 40 g of bait /secured bait point separated by 1-2 m.

The products, organisms or objects to be protected are public and private buildings, and farms, open areas.

➤ **Minor change application (FANGA 5 CEREALES 25)- 2022**

The product FANGA 5 CEREALES 25 (same as the product FANGA RAT-DICAL TECH), containing 0.0025 % w/w brodifacoum, was authorised for use against *Mus musculus*, *Rattus norvegicus* and *Rattus rattus*, in and around buildings and outdoor environments (open areas and waste dumps) by professional users and in buildings against *Mus musculus* and in and around buildings against *Rattus norvegicus* and *Rattus rattus* by non-professional users, with a shelf-life of 24 months.

The validated application rates were the following:

- Rats (*Rattus norvegicus*, *Rattus rattus*): 100 g of bait/secured bait point separated by 5-10 m.
- Mice (*Mus musculus*): 40 g of bait/secured bait point separated by 1-2 m.

In the frame of the minor change application, the applicant requires an authorization for the product FANGA 5 CEREALES 25 with a change in composition: a change of the maize grain to a mixture of grains.

The application rates and uses claimed by the applicant are the same the previous authorization of the product.

New efficacy studies were conducted with FANGA 5 CEREALES 25 (same composition as claimed for this minor change), on *Rattus norvegicus*, *Rattus rattus* and *Mus musculus*, with aged bait, to confirm the efficacy of the biocidal product for these species.

All the new efficacy studies provided are presented in annex 11.

#### 2.5.4 Mode of action including time delay

Brodifacoum acts as a vitamin K antagonist. It interferes with the regeneration of prothrombin disturbing the normal blood clotting mechanisms and increasing tendency to bleed.

The main site of its action is the liver, where several of the blood coagulation precursors under vitamin-K dependent post translation processing take place before they are converted into the respective procoagulant zymogens.

Brodifacoum works by blocking the regeneration of vitamin K 2,3-epoxide to vitamin K hydroquinone. Since the amount of vitamin K in the body is finite, the progressive block of the regeneration of vitamin K will lead to an increasing probability of a fatal haemorrhage.

Death of target animal occurs 7 to 11 days after ingestion.

#### 2.5.5 Occurrence of resistance - resistance management / Unacceptable effect

Resistance to the first generation anticoagulants has been widely reported in both *Rattus norvegicus* and *Mus domesticus* since the late 1950's. The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%.

The enzyme vitamin K 2, 3 epoxide reductase (VKOR) is the target for anticoagulants. Modifications in the protein structure due to polymorphisms on the gene coding the VKOR may induce anticoagulant resistance. Most resistant strains are characterised by one single nucleotide polymorphism (SNP). These SNPs cause the exchange of one amino acid in the VKOR enzyme. The biochemical mechanism of anticoagulant resistance has been studied in several geographic strains/VKORC1-variants of the Norway rat. Amino acid substitutions in the VKOR seem to alter its structure and function, resulting in decreased sensitivity to anticoagulant inhibition, depending on strain characteristics.

For house mice, a dominant autosomal warfarin-resistance gene was determined on chromosome 7 in house mice. Three VKORC1 sequence variants mediating resistance to anticoagulants seem to be widely distributed. House Mice carrying the homozygous of one of these variants (Y139C) were found highly resistant to warfarin and bromadiolone.

For roof rats, experiments on warfarin resistant rats indicated considerable instability in the resistance and suggested a multifactorial basis for resistance.

Some degree of resistance to difenacoum has been reported in the UK, Denmark, France and Germany but this is usually found in certain populations of rodents highly resistant to first generation anti-coagulants (Greaves et al., 1982 ; Lund, 1984 ; Pelz et al. 1995 ). The resistance factor tells how much the anticoagulant dose has to be multiplied to kill resistant individuals compared to sensitive ones. The resistant factors for difenacoum in the brown rats ranged from 1.1 to 8.6 (Greaves and Cullen-Ayres 1988 ). The study included rats resistant to warfarin and difenacoum. Resistance factors for warfarin ranged from approx. 50 to 2300. Greaves et al. (1982) reported a fivefold difenacoum dose needed to kill difenacoum resistant rats. Considerable doubt exists as to the significance of

reports in UK of resistance to second-generation anticoagulants and in the UK control failures with the second-generation products are increasingly being attributed to baiting problems rather than physiological resistance (Greaves and Cullen Ayres, 1988; Quy et al. 1992a,b ).

Studies carried out in different European countries, in the UK more particularly (Kerins et al, 2001; see annex 1) revealed the occasional occurrence of cross-resistances to second-generation anticoagulants, such as difenacoum and bromadiolone on resistant brown rats populations to coumafene. Moreover, a publication (Baer et al., 2012) has demonstrated that the majority (91%) of warfarin resistant rat trapped in East and West parts of Belgium were also resistant to bromadiolone. The rats trapped in the region of Flanders (Northern Belgium) carried mutation Y139F. This mutation is found extensively in France where it also confers resistance to bromadiolone (Grandemange et al., 2009). The same mutation was also found in UK (Prescott et al., 2011) where applications of bromadiolone had been unsuccessful. Difenacoum is also thought to be partially resisted by rats which carry Y139F.

House mice carrying the homozygous Y139C sequence variant were found to be highly resistant to warfarin and bromadiolone.

So, resistance to second generation anticoagulant rodenticides should not be minimized.

An exhaustive study carried out at the French and European levels could enable to point-out resistant areas with first generation anticoagulants and potential cross-resistances to second-generation anticoagulants. It is one of the actions undertaken since 2010 in France by a group of scientists (Rodent program “impacts of anticoagulants rodenticides on ecosystems-adaptations of target rodents and effects on their predators”).

The document CropLife International (RRAC 2015) provides guidance to advisors, national authorities, professionals, practitioners and others on the nature of anticoagulant resistance in rodents, the identification of anticoagulant resistance, strategies for rodenticide application that will avoid the development of resistance and the management of resistance where it occurs.

The following are the essential elements of an effective program: survey, use of physical and chemical control techniques, environmental management, record keeping, monitoring and review.

The authorization holder should report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management at the renewal of the product.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

### 2.5.6 Evaluation of the label claim

For the first authorisation, French competent authorities (FR CA) assessed that the product FANGA RAT-DICAL TECH has shown a sufficient efficacy for the control of house mice (*Mus musculus*). The label has to be reviewed accordingly.

Label has to be revised as following:

- Inspections of bait points have to be made 3 days after the first application then weekly for use in building.

The application rates validated are the following (see also Annex 0b):

House mice: 50 g grains/secured bait point separated by 1-2 m

The product FANGA RAT-DICAL TECH is supplied in sachets of different amounts. The amount of bait per bait station or bait points must not exceed the recommended application rates.

➤ **Major change - 2016**

Regarding the major change and post authorisation requirements, French competent authorities (FR CA) assessed that the product FANGA RAT-DICAL TECH has shown a sufficient efficacy for the control of *Rattus norvegicus*, *Rattus rattus* and *Mus musculus*.

The application rates validated are the following:

House mice: 40 g baiting point separated by 1 - 2 m

Rats: 200 g per baiting point separated by 5 - 10 m.

➤ **Renewal application - 2017**

Regarding the renewal, French competent authorities (FR CA) assessed that the product FANGA RAT-DICAL TECH has shown a sufficient efficacy for the control of mice (*Mus musculus*) and rats (*Rattus norvegicus* and *Rattus rattus*) 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 application – 2018**

French competent authorities (FR CA) consider that the product **FANGA RAT-DICAL TECH** has shown a sufficient efficacy for the control of mice (*M. musculus*) and rats (*R. norvegicus* and *R. rattus*).

The application rates validated are the following:

- Rats (*Rattus norvegicus* and *Rattus rattus*): 100 g of grains/secured bait point separated by 5-10 m
- Mice (*Mus musculus*): 40 g of grains/secured bait point separated by 1-2 m.

➤ **Minor change application (FANGA 5 CEREALES 25)- 2022**

French competent authorities (FR CA) consider that the product FANGA 5 CEREALES 25 has shown a sufficient efficacy for the control of mice (*Mus musculus*) and rats (*Rattus norvegicus* and *Rattus rattus*) for a shelf-life up to 2 years.

The application rates validated are the following:

- Rats: 100 g of grains/secured bait point separated by 5-10 m
- Mice: 40 g of grains/secured bait point separated by 1-2 m.

## **2.5.7 Conclusion of the efficacy assessment**

➤ **Renewal application - 2017**

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

➤ **Minor change application – 2018**



The product **FANGA RAT-DICAL TECH** has shown sufficient efficacy and can be used for the control of rats (*Rattus norvegicus* and *Rattus rattus*) at the claimed application rate of 100 g / bait station:

- For professional users: in and around buildings, and outdoor environments (open areas, and waste dumps);
- For non-professional users: in and around buildings.

- **Minor change application (FANGA 5 CEREALES 25)- 2022**

The product **FANGA 5 CEREALES 25** has shown sufficient efficacy and can be used for the control of mice (*Mus musculus*) and rats (*Rattus norvegicus* and *Rattus rattus*) at the claimed application rate of 40 g / bait station for mice and 100 g / bait station for rats, with a shelf-life up to 2 years:

- For professional users: in and around buildings, and outdoor environments (open areas, and waste dumps);
- For non-professional users: indoor (mice and rats) and around buildings.(rats only)

## 2.6 Description of the intended use

In the frame of the renewal of the authorisation, the product FANGA RAT-DICAL TECH is intended to be used for the control of rodents in and around buildings, in open areas by professional and non professional users, and in waste dumps and landfills by professional users only. The target species claimed by the applicant are mice and rats.

Efficacy is demonstrated at the following dosage

- Rats: 200 g paste/secured bait point separated by 5-10 m
- House mice: 40 g paste/secured bait point separated by 1-2 m

➤ **Major change application - 2016**

FANGA RAT-DICAL TECH is intended to be used to control rats and mice in and around buildings, open areas and waste dumps and landfills and to control also rats in sewers. The target organisms to be controlled are *Mus musculus*, *Rattus norvegicus* and *Rattus rattus*.

The application rates validated are the following:

- House mice: 40 g baiting point separated by 1-2 m
- Rats: 200 g per baiting point separated by 5 -10 m.

➤ **Renewal application - 2017**

No change has been claimed.

➤ **Minor change application – 2018**

A new application rate of **FANGA RAT-DICAL TECH** against rats is claimed by the applicant : 100 g.

➤ **Minor change application (FANGA 5 CEREALES 25)- 2022**

A new formulation of the product is claimed by the applicant: a change of the maize grain to a mixture of grains.

## 2.7 Risk assessment for human health

### 2.7.1 Hazard potential

#### 2.7.1.1 Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements.

The results of this toxicological assessment can be found in the **combined Assessment Report**. Brodifacoum (CAS no. 56073-10-0) was notified as an existing active substance, by Syngenta Limited and Activa / Pelgar Brodifacoum and Difenacoum Task Force<sup>11</sup>, hereafter referred to as the “AS applicants”, in product-type 14. A combined assessment report was available on December 2010.

The following corresponds to the summary of the effect assessment available in the combined assessment report of brodifacoum.

- **Toxicokinetics**

#### **Data from Syngenta:**

*Brodifacoum* (0.21 mg/kg bw) administered orally to rats was rapidly absorbed ( $T_{max}$  =8h;  $C_{max}$  16.1 ng/ml whole blood). The levels declined slowly and about 10% (1.3 ng/ml) was still present at 10 days after dosing. Almost all (82.5 %) the radioactivity in whole blood was found to be associated with the plasma. Based on the radioactivity still associated to the animal tissues, 10 days after the treatment, the **oral absorption was > 75%**. After a single oral dose of 10 mg/kg of *Brodifacoum* about 64.0% was absorbed and could be accounted for in the liver, carcass and bile 48h after dosing. The rest was recovered in the faeces, as unabsorbed material.

After absorption the product was widely distributed. 10 days after dosing the proportion of the retained dose was highest in the liver (22.8 %), followed by the pancreas (2.3 %), and then the kidney (0.8 %), heart (0.1 %) and spleen (0.2 %). The remainder of the dose ( $\cong$ 50%) was in the carcass and skin.

*Brodifacoum* was only partially metabolised. 31.3% and 19.6% of the residues in the carcass and liver, respectively, was unchanged *Brodifacoum*. Two more polar metabolites were detected in the bile, the major one being identified as the glucuronide.

*Brodifacoum* shows a high potential for bioaccumulation: in all studies undertaken and at all dose levels tested, the liver retained the largest % of the dose, even very long time after dosing.

Analyses of the rat livers from the 90 day feeding study, indicate a non-linear accumulation of *Brodifacoum* vs dose and time.

A small amount (11 – 14%) of the radioactivity was slowly eliminated in urine and faeces over 10 days following a single oral dose of 0.25 mg/kg. Biliary and renal routes are of equal significance in the elimination of *Brodifacoum*. The rate of elimination as given by the biological half-life, was calculated to be 150 – 200 days.

The elimination from the liver was biphasic at higher doses. There was a rapid phase (days 1-4) which also corresponded to a reduction in clotting factor synthesis, followed by a slower terminal phase (days 28-84) during which blood clotting function was normal. The half-life of elimination from the liver during the rapid and the slow phase was  $\cong$ 4 and 128 days, respectively. At low dose levels, clotting factor synthesis was unaffected indicating that probably only the slow elimination phase was present in the liver. The half-life of *Brodifacoum* in the liver was calculated in the range of 282-350 days.

Dermal absorption was assessed by using a formulation (ready-for-use pellet bait) containing 0.0048% *Brodifacoum* w/w tested in vitro test on human skin samples. Over the entire 24 h exposure *Brodifacoum* (determined by LC-MS-MS) was found below the LOQ in the receptor fluid (<3.53% of the applied dose) and in the epidermis (<1.64%), after tape stripping. The applied dose was readily removed by mild skin washing and recovered ( $108 \pm 6.25\%$ ) in the washing fluid. **A ‘surrogate value’**

<sup>11</sup> Syngenta Limited and Activa / Pelgar Brodifacoum and Difenacoum Task Force Combined Assessment Report according to the procedure of Directive 98/8/EC, active substance in biocidal products, brodifacoum CAS n°56073-10-0, product type 14 (rodenticides), RMS Italy, Revision2: November 2010.

of 5% dermal absorption was calculated by summing up the amount in the receptor fluid and in the epidermis after tape stripping, which can be considered as systemically available material. This value has been taken forward to the risk characterization as the worst case, also taking into account that the exposure period exceeds the usual time (*i.e.* 8 hours) of professional handling.

#### **Data from Activa/PelGar:**

Read across to data from some related 2<sup>nd</sup> generation anticoagulants (*i.e.* *Difenacoum*, *Flocoumafen*) is requested for ADME data, including dermal absorption, and has been applied for other end-points by the RMS.

Beside the similar mode of action, the read across is supported by bridging studies demonstrating the similarity in physico-chemical and toxicological properties of these substances which are presented up-front to Doc. IIA- Section 3.

Anticoagulant rodenticides including *Brodifacoum* are rapidly absorbed via the gastro-intestinal tract and oral absorption is assumed to be 100%, on the basis of amount of radioactivity recovered in the excreta and retained in the tissues. The major route of elimination after oral administration is via the faeces, both as polar metabolites and parent compound. *Brodifacoum* is widely distributed and bioaccumulates in the liver with minor concentrations in the kidney.

Elimination processes are very slow with 50-75% of the administered dose being retained in the liver ( $t_{1/2}$  for hepatic residues more than 200 days).

The metabolism of *Brodifacoum* is limited, although in repeated dose studies evidence of induction of metabolism was reported, with increasing levels of radioactivity associated to polar metabolites recovered in the urine. The toxicologically relevant chemical species is the parent compound.

No study on dermal absorption of *Brodifacoum* has been presented. *Brodifacoum* is expected to be slowly absorbed through the skin, due to the lipophylicity of the molecule, allowing passive transport through the membrane. The read across principle can be applied, based on the close structural relationship, the similar physico-chemical properties and the same mode of action displayed by *Brodifacoum* towards other 2<sup>nd</sup> generation anticoagulants, such as *Difethialone* and *Difenacoum*. A dermal absorption value =4% has been adopted for *Difethialone*, whereas in the case of *Difenacoum* two different values have been used for risk characterisation depending on the type of formulation, that is 3% (pellets and grains) or 0.047% (wax block bait).

In the CAR, by applying the read across from data on a structurally related 2<sup>nd</sup> generation anticoagulant *Difenacoum*, a 3% dermal absorption value was adopted for the exposure calculation. This value was calculated from a dermal absorption study testing a pellet formulation containing *Difenacoum* as active substance.

#### **Conclusion on toxicokinetics:**

An almost complete oral absorption can be considered, on the basis of amount of radioactivity recovered in the excreta and retained in the tissues. *Brodifacoum* is widely distributed and bioaccumulates mainly in the liver with lower concentrations in the kidney. Hepatic bioaccumulation of *Brodifacoum* is a non-linear vs dose and time. The elimination kinetic from the liver was biphasic, with an half-life in the range of 282-350 days. The excretion after oral administration is very slow (11 – 14% in 10 days), occurring via the urine and the bile, both as polar metabolites (glucuronide) and parent compound. The metabolism of *Brodifacoum* is limited and the toxicologically relevant chemical species is the parent compound.

Concerning the dermal absorption value to be used in the risk characterisation for wax block bait, in the Combined Assessment Report for *Difenacoum* (September 2009) a value of 0.047% was proposed. Therefore, on the basis of the available study and reading across from data on other 2<sup>nd</sup> generation anticoagulant rodenticides, two different values should be used for risk characterisation depending on the type of formulation: 5% (pellets and grains) or 0.047% (wax block bait).

- **Acute effects**

**Data from Syngenta:**

*Brodifacoum* was very toxic to rats and mice with similar oral LD<sub>50</sub> of about 0.4 mg/kg bw to the male rat and mouse. *Brodifacoum* is also acutely toxic by the dermal and inhalation routes. Death was the result of internal haemorrhage.

*Brodifacoum* does not fulfil the EU criteria for classification as a skin or eye irritant, but is able to cause skin sensitization in guinea pig and fulfils the EU criteria for classification as a skin sensitizer.

**Data from Activa/PelGar:**

*Brodifacoum* is very toxic if swallow (oral LD<sub>50</sub> <5 mg/kg bw) or in contact with skin (dermal LD<sub>50</sub>= 7.48 mg/kg bw in rat females; even lower in males).

The waiving for the inhalation toxicity study has been accepted due to low vapour pressure of *Brodifacoum* and data on dustiness and particle size, indicating that the potential for inhalation is limited in addition to ethical and animal welfare reasons. However, based on data with structurally related compounds with the same mechanism of action (*i.e.* 2<sup>nd</sup> generation anticoagulants), it is expected that the substance is also highly toxic after inhalation.

*Brodifacoum* is not irritant to the skin or eyes of rabbits and showed no sensitizing potential in a LLNA study in mice.

**Conclusion on acute effects:**

*Brodifacoum* is very toxic after oral administration and also via the dermal and inhalation routes. Death was the result of internal haemorrhage. Classification with T+; R26/27/28; 'Very toxic by inhalation, in contact with skin and if swallowed' is warranted.

*Brodifacoum* does not fulfil the EU criteria for classification as a skin or eye irritant. Although showed no sensitizing potential in a LLNA study in mice, it was able to cause skin sensitization in guinea pig and fulfils the EU criteria for classification as a skin sensitizer.

- **Repeated Dose Effects**

**Data from Syngenta:**

Repeated dose oral studies show that in the rat and in the dog, the clinical signs, haematological and post mortem data were consistent with the known pharmacological action of *Brodifacoum*: impairment of the clotting cascade and increased prevalence of haemorrhage leading to death. There were no indications of other secondary toxicities: any of the other parameters including histopathological analysis revealed no treatment related alterations.

The subchronic 90-day oral toxicity allowed the derivation of the lowest repeated toxicity NOEL= 0.001 mg/kg bw/day. In this study, no treatment related effects on haematological parameters were evidenced at any dose, after 45 days, but statistically significant increases in both the kaolin-cephalin time (KCT) and the prothrombin time (PT) were measured at the highest dose level, 0.004 mg/kg bw/day after 90 days. Based upon this effect on prothrombin times and based on haemorrhagic changes seen at necropsy, the NOEL was set at the next lowest dose, 0.001 mg/kg bw/day.

Classification with T; R48/23/24/25 "Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed" is warranted based on these data plus extrapolation from the acute data for the dermal and inhalation route of exposure.

**Data from Activa/PelGar:**

Repeated oral exposure to *Brodifacoum* resulted in clinical signs and toxicity consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent (lethal haemorrhages). The overall NOAEL for subchronic oral toxicity is 0.04 mg/kg/day.

No data have been submitted on dermal repeated toxicity. On the basis of both physico-chemical properties and *Brodifacoum* mode of action it can be anticipated that subchronic effect due to prolonged skin contact should not be disregarded.

No data on repeated inhalation toxicity have been submitted. As indicated by the low vapour pressure, dustiness and particle size, the potential for inhalation is low and the request for a repeated dose inhalation toxicity study is not considered justified also based on ethical and animal welfare reasons.

However, based on the results of the acute dermal and inhalation toxicity studies, route-to-route extrapolation, consistently with the decision adopted for *Difenacoum* (being the read across accepted for other end-points), it is justified to assume a similar concern for serious damage to health by prolonged exposure through dermal and inhalation routes also.

- **Genotoxicity**

**Data from Syngenta:**

*Brodifacoum* was tested in *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98, TA 100, TA 1538, with and without S9-mix, up to 5000 mg/plate, with negative results. No clastogenic activity was observed in the *in-vitro* cytogenetic assay in human lymphocytes, performed with and without metabolic activation, up to cytotoxic doses. The *in vitro* mammalian cell mutation assay in mouse lymphoma L5178Y cells also resulted negative, with and without S9-mix, while cytotoxic effects were observed at the highest doses. The AS applicant submitted also an *in vitro* UDS test and in an *in vitro* cell transformation assay, but because of several methodological and reporting shortcomings, they were considered of limited scientific significance. An *in vivo* mouse micronucleus test gave negative results. The studies submitted were rather dated, therefore they were not always compliant with the current guidelines. However a genotoxic potential of the active substance can be reliably ruled out.

**Data from Activa/PelGar:**

*Brodifacoum* was tested for genotoxic activity in the bacterial reverse mutation test in *Salmonella typhimurium* in strains TA 98, TA 100, TA 102, TA 1535 and TA 1537, up to 5000 µg/plate, with and without metabolic activation (S9-mix). No genotoxic activity was observed in any bacterial strain. The substance resulted negative up to cytotoxic concentration also in the gene mutations assay in L5178Y mouse lymphoma cells, with and without S9-mix, and in the *in vitro* mammalian chromosome aberration test in human lymphocytes (50% mitotic inhibition at the maximum dosage tested).

- **Carcinogenicity/chronic toxicity**

Carcinogenicity and long-term toxicity studies were waived as infeasible and unnecessary.

- **Reproductive and developmental toxicity**

**Data from Syngenta:**

*Brodifacoum* did not induce developmental effects in two adequate prenatal toxicity studies in the rat and rabbit, respectively.

In particular, in the rat studies maternal hemorrhages were observed at dose levels > 0.01 mg/kg bw (NOEL 0.001 mg/kg bw) whereas no effects on conceptuses were detected up to the top dose level of 0.02 mg/kg bw. In the rabbit study, the top dose of 0.005 mg/kg b.w caused a high proportion of maternal deaths, whereas no significant effects on litters were observed. In spite of these findings, a provisional decision has been made at the Technical Meeting of Classification and Labelling that [R61] should be applied to all anticoagulant active substances on the basis of analogy to *Warfarin*.

**Data from Activa/PelGar:**

There was no evidence of developmental toxicity effects up to the dose levels of 0.04 and 0.004 mg/kg bw in rats and rabbits, respectively. In rabbit dams an increase in kaolin-cephalin and prothrombin time was present at 0.004 mg/kg bw (NOAEL 0.002 mg/kg).

Whereas it is suggested that two-generation studies may not be needed for anticoagulant rodenticides, a two-generation study on rat was submitted: findings confirmed those of developmental toxicity, both qualitatively (parental toxicity with haemorrhages, no reproductive or developmental effects in the absence of general toxicity) and quantitatively (NOAEL: 0.001 mg/kg bw).

Since the conventional OECD Guideline 414 may have limitations in the detection of possible developmental effects of coumarin related compounds, and in spite of these findings, a provisional decision has been made at the Technical Meeting of Classification and Labelling that [R61] should be applied to all anticoagulant active substances on the basis of analogy to *Warfarin*.

- **Neurotoxicity**

**Data from Syngenta:**

None of the acute or subchronic performed tests gave any indication for a potential neurotoxic effect of *Brodifacoum*.

**Data from Activa/PelGar:**

The toxicological studies do not indicate any neurotoxic effects.

**Conclusion on repeated dose effects:**

Repeated oral exposure to *Brodifacoum* resulted in clinical signs and toxicity consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent (lethal haemorrhages). The NOEL for subchronic oral toxicity is in the range 0.04 -0.001 mg/kg/day (the lowest values identified with sensitive end-points, such as increases in both the kaolin-cephalin time and the prothrombin time). Based on results from the acute dermal and inhalation toxicity studies, route-to-route extrapolation, consistently with the decision adopted for *Difenacoum*, it is justified to assume serious damages associated to prolonged exposure through dermal and inhalation routes also. Therefore, classification with T; R48/23/24/25 "Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed" is warranted.

**Conclusion on Genotoxicity and Carcinogenicity:**

*Brodifacoum* displayed no mutagenic activity in a standard range of genotoxicity tests. No long-term carcinogenicity study was submitted by the two AS applicants. In fact, chronic toxicity studies were not considered to be technically feasible due to the specific action of the active substance on the test/target species. However, the anticoagulant action is apparently the only pharmacological action of *Brodifacoum*. The active substance has no structural alerts for carcinogenicity and no concern about possible non-genotoxic carcinogenic potential can be derived from the toxicological studies. Therefore the justifications of both AS applicants for not-submission of carcinogenicity data was considered acceptable.

**Conclusion on Reproductive toxicity:**

Reproductive and developmental toxicity studies on *Brodifacoum* did not reveal any specific effects. General toxicity effects were consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent. The lowest NOAELs for rabbits and rats were 0.002 and 0.001 mg/kg bw.

In spite of these findings, a provisional decision has been made at the Technical Meeting of Classification and Labelling that [R61] should be applied to all anticoagulant active substances on the basis of analogy to *Warfarin*.

None of the acute or subchronic performed tests gave any indication for a potential neurotoxic effect of *Brodifacoum*.

The following corresponds to the summary of the derivation of the AELs from the combined Assessment Report of brodifacoum:

**Data from Syngenta:**

The Acceptable Exposure Level for acute exposure (AEL<sub>acute</sub>) was based on the maternal NOEL from developmental study of 0.001 mg/kg bw/day (rat, maternal effect). A safety factor of 300 (10 for intra-species variability x 10 for inter-species variability x 3 additional factor for severity of effects). The AEL<sub>acute</sub> results to be of  $3.3 \times 10^{-6}$  mg/kg/day.

The Acceptable Exposure Level for repeated exposure (AEL<sub>chr</sub>) was based on a subchronic NOEL from a 90-day oral rat study of 0.001 mg/kg bw/day. A safety factor of 300 (10 for intra-species variability x 10 for inter-species variability x 3 additional factor for severity of effects). The AEL<sub>chr</sub> results to be of  $3.3 \times 10^{-6}$  mg/kg/day.

**Data from Activa/PelGar:**

The Acceptable Exposure Level for acute exposure (AEL<sub>acute</sub>) was based on NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day. A safety factor of 300 (10 for intra-species variability x 10 for inter-species variability x 3 additional factor for severity of effects). The AEL<sub>acute</sub> results to be of  $6.7 \times 10^{-6}$  mg/kg bw/d.

The Acceptable Exposure Level for repeated exposure (AEL<sub>chr</sub>) was based on NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day. A safety factor of 300 (10 for intra-species variability x 10 for inter-species variability x 3 additional factor for severity of effects). The AEL<sub>chr</sub> results to be of  $3.3 \times 10^{-6}$  mg/kg bw/day.

TMIII09 agreed to derive AEL<sub>medium term</sub> consistently with what decided for the other AVK rodenticides. Therefore, AEL<sub>medium term</sub> was calculated from the NOAEL of 0.002 mg/kg bw/day (developmental oral toxicity study in rabbit) divided by an Assessment Factor of 300 (10 for interspecies x 10 for intraspecies x 3 additional factor for severity of effects). The AEL<sub>medium term</sub> results to be of  $6.7 \times 10^{-6}$  mg/kg bw/day.

**Conclusions:**

The following AELs should be considered in the risk characterization for *Brodifacoum*:

- AEL<sub>acute</sub> of  $3.3 \times 10^{-6}$  mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)
- AEL<sub>medium term</sub> of  $6.7 \times 10^{-6}$  mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day

- AEL<sub>chr</sub> of  $3.3 \times 10^{-6}$  mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

#### 2.7.1.2 Toxicology of the substance(s) of concern

Considering the following definition of a substance of concern set in the the biocidal product FANGA RAT-DICAL TECH contains no substance of concern.

##### ➤ Renewal application - 2017

Considering the following definition of a substance of concern set in the Guidance on the BPR Volume III Human Health – Part B Risk Assessment, the biocidal product FANGA RAT-DICAL TECH contains no substance of concern.

#### 2.7.1.3 Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.

The basis for the health assessment of the biocidal product is laid out in Annex 5 "Toxicology – biocidal product".

Acute oral and dermal toxicity, skin and eye irritation and skin sensitisation studies have been performed with the product FANGA BLOC SP PRO, a block formulation containing 0.005% of brodifacoum. The compositions of FANGA BLOC SP PRO and FANGA RAT-DICAL TECH are considered similar.

##### 2.7.1.3.1 Percutaneous absorption

A new study of percutaneous absorption has been submitted by TRIPLAN. A percutaneous absorption value of 0.647% has been set for the difenacoum based on this *in vitro* study realised on human skin with pellets containing 0.005% difenacoum. It has been considered that this dermal absorption value could be extrapolated to FANGA RAT-DICAL TECH.

##### ➤ Renewal application - 2017

The dermal absorption of difenacoum formulated as pellet bait (containing 0.005% difenacoum) was investigated *in vitro* using human skin. The measured samples were below the limit of detection or quantification, but as a worst case, the corresponding validated LOQ value was used for the calculations of dermal absorption. The percentage of absorbed difenacoum was 0.647% (receptor fluid + epidermis + dermis + stratum corneum). The total recovery of difenacoum was 97.3% when skin discs were exposed to 5 mg/cm<sup>2</sup> of the product (equivalent to 250 ng a.s./cm<sup>2</sup>) for 24 hours.

This study has been evaluated according to the EFSA guidance on dermal absorption and is considered valid.

##### 2.7.1.3.2 Acute toxicity

###### Oral route

No mortality occurred during the study (daily examination during 14 days).

No clinical signs related to the administration of the test item were observed.

The body weight evolution of the animals remained normal throughout the study.



The macroscopically examination of the animals at the end of the study did not reveal treatment-related changes.

LD<sub>50</sub> of the test item is higher than 2000 mg/kg/bw.

Route	Method	Species	Dose level	LD50
Oral	OECD 423	Rat 3 males and 3 females	2000mg/kg bw	>2000 mg/kg bw

Dermal route

No mortality occurred during the study.

The body weight evolution of the animals remained normal throughout the study.

Neither cutaneous reactions nor systemic clinical signs related to the administration of the test item were observed.

The macroscopically examination of the animals at the end of the study did not reveal treatment-related changes.

LD<sub>50</sub> of the test item is higher than 2000 mg/kg/bw.

Route	Method	Species	Dose level	LD50
Dermal	OCDE 402	Rat 5 males and 5 females	2000 mg/kg bw	>2000 mg/kg bw

Based on the above-mentioned results, no classification is required for FANGA RAT-DICAL TECH.

**2.7.1.3.3 Irritation and corrosivity**

Based on the results of the irritation assays on rabbit's skin and eye, no classification is required for FANGA RAT-DICAL TECH.

Route	Method	Species	Dose level	
Skin	OECD 404	Rabbit NZ 3 females	0.5 g	Not irritant
Eye	OCDE 405	Rabbit NZ 3 females	0.1 g	Not irritant

**2.7.1.3.4 Sensitisation**

Based on the results of the irritation assays on rabbit's skin and eye (LLNA), no classification is required for FANGA RAT-DICAL TECH.

Route	Method	Species	Dose level	
Skin	OECD 429	Mice16 (12 for the treated groups)	Topical way of induction:	Not skin sensitizing

			5, 10, 25% of the test item	
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**2.7.1.3.5 Other studies**

No other studies are performed on FANGA RAT-DICAL TECH.

**2.7.2 Human exposure assessment**

FANGA RAT-DICAL TECH (PT14) is a ready-to-use rodenticide containing 0.0025 % of brodifacoum (pure: 950 g/kg). Baits are packaged in sachet for professional users. The baits are placed in bait stations (tamper-resistant bait boxes or covered bait stations) out of reach of children and domestic animals.

No new human exposure studies have been submitted.

**2.7.2.1 Identification of main paths of human exposure towards active substance from its use in biocidal product**

The potential for exposure to brodifacoum grain baits is summarised in the table below:

**Table 3: Main paths of human exposure**

<b>Exposure path</b>	<b>Industrial use</b>	<b>Professional use</b>	<b>General public</b>	<b>via the environment</b>
Inhalation	Not relevant	Potentially significant	Negligible	Negligible
Dermal	Not relevant	Potentially significant	Potentially significant	Negligible
Oral	Not relevant	Negligible	Potentially significant	Negligible

**2.7.2.2 Direct exposure as a result of use of the active substance in biocidal product**

**2.7.2.2.1 Exposure of professional users**

*In Annex 6 „Safety for professional operators“, the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out.*

FANGA RAT-DICAL TECH is used for the control of rats and mice for use indoors, with the purpose of protecting human food and animal feedstuffs, and for human hygiene.

As the product is only supplied in sachets, exposure during decanting and loading phases is considered as negligible.

Only dermal exposure during cleaning phase is taken into account.

In the dossier, TRIPLAN assessed the human exposure based on the TNsG on human exposure, section 7.2 of part 3 – June 2002. This document only contains a series of examples for human exposure assessment and should not be considered as reference data. Therefore, since TRIPLAN provided a letter of access for the unpublished CEFIC study “Chambers J.G. and Snowdon P.J. Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits”,

the FR CA decided to base the human exposure assessment for professionals on this study as done by the RMS (Italy) of the active substance in the Assessment report on brodifacoum. This study examined the inhalation and dermal exposures associated with all activities involved in using a grain bait (decanting material from a large container to a pail, filling and placing bait points, and clean-up and disposal of bait points). The used grain bait containing coumatetralyl was selected as a worst case representative product of all cereal-based rodenticide baits. In this study, 10 replicates were performed at 1, 5 and 10 manipulations. Therefore, the FR CA decided to use the exposure estimations issued from the CEFIC study for the assessment of FANGA RAT-DICAL TECH.

Additionally, the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant), agreed at TMIII 2010 and the HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011 were taken into account for the estimation of exposure for professionals.

Based on the CEFIC study and taking into account the HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg product/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 16 cleanings in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010).

The following parameters were taken into account:

- active substance in product: 0,0025 % (w/w) ;
- dermal absorption: 0,647 % ;
- body weight: 60 kg ;

Therefore, considering 16 cleanings per day, the systemic dose of brodifacoum on fingers/hands during loading is  $1.6 \times 10^{-7}$  mg/kg bw/day for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

**In conclusion, the total systemic dermal exposure is set at  $1.6 \times 10^{-7}$  mg/kg bw/day without PPE for the control of rats and mice.**

➤ **Major change application - 2016**

In the reference product PAR, FANGA RAT DICAL TECH was presented as a ready-to-use grain baits in sachet containing 0.0025 % of brodifacoum (pure: 950 g/kg) packaged in sachet for professional users and indoor against mice (50g per bait point).

The applicant asked the addition for professionals of:

- The outdoor use for mice: in and around buildings, open areas, waste dumps, landfills and sewers
- Rats as new target indoor and outdoor (in and around buildings, open areas, waste dumps, landfills and sewers) (200g per bait point)
- Use of loose grains

The applicant asked also the addition of non-professional and the uses as follow:

- Grains in sachet only
- Target against rats (200 g per bait point) and mice (50 g per bait points)
- Indoor and outdoor (In and around buildings, open areas)

Composition of the product did not change, so the previous dermal absorption in PAR (0.647 %) was used.

Exposure of professional users

➤ **For professional users of loose grains:**

As a worst case, exposure has been assessed considering FANGA RAT DICAL TECH at the maximum recommended dose of 200 g for the use against rats as loose grains.

This approach also covers human exposure during the control of mice (50 g) and the use of grains in sachet against rats and mice as the sachet will reduce exposure.

• **Decanting phase for loose grains**

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, **for professional users manipulating the product in bulk**, the amount of product on fingers/hands **during the decanting of 3 kg of grain** was 52.3 mg of biocidal product, corresponding to 219.66 mg of biocidal product during the decanting phase for 12.6 kg of grain manipulated per day.

The systemic dose of brodifacoum on fingers/hands during decanting is  $5.92 \times 10^{-7}$  mg/kg bw/d.

The product being packaged in bulk, professional users may be potentially exposed by inhalation during decanting of grain bait. Considering an exposure of 3 minutes for 3 kg of biocidal product, 13 minutes should be taken into account for 12.6 rounded at 13 kg of product, an air concentration of  $9.62 \text{ mg/m}^3$ , an inhalation rate of  $1.25 \text{ m}^3/\text{hour}$  and inhalation absorption of 100%, inhalation exposure product is 2.61 mg of biocidal product per day. This is corresponding to a potential systemic dose of brodifacoum during decanting of  $1.09 \times 10^{-6}$  mg/kg bw/d.

In conclusion, for professional users manipulating the biocidal product in bulk, the total systemic exposure is set at  $1.68 \times 10^{-6}$  mg/kg bw/d without PPE.

• **Loading phase for loose grains**

**During the loading phase**, the amount of product on fingers/hands was 2.04 mg bp/loading. For the assessment of 63 loadings per day (agreed number of loading in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010), the amount of biocidal product on fingers/hands was 128.52 mg bp/day. The corresponding systemic dose of brodifacoum on fingers/hands during loading phase is  $3.46 \times 10^{-7}$  mg/kg bw/d.

• **Cleaning phase for loose grains**

**During the cleaning phase**, the amount of product on fingers/hands was 3.79 mg bp/cleaning. For the assessment of 16 cleanings per day (agreed number of cleaning in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010), the amount of biocidal product on fingers/hands was 60.64 mg bp/day. The corresponding systemic dose of brodifacoum on fingers/hands during cleaning phase is  $1.63 \times 10^{-7}$  mg/kg bw/d.

• **Total exposure for loose grains:**

In conclusion, the total systemic dermal exposure is set at  $1.1 \times 10^{-6}$  mg/kg bw/day without PPE for the control of rats.

The total systemic exposure resulting from inhalation is set at  $1.09 \times 10^{-6}$  mg/kg bw/d without PPE.

→ Therefore, the combined total exposure (inhalation + dermal) is set at  $2.19 \times 10^{-6}$  mg/kg bw/d without any individual protective equipment.

*In Annex 4: Safety for professional operators“, the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out.*

<b>Tier</b>	<b>Inhalation exposure</b>	<b>Dermal exposure</b>	<b>Total exposure</b>
PPE	Systemic dose	Systemic dose	Systemic dose
	mg a.i. / kg bw /day	mg a.i. / kg bw /day	mg a.i. / kg bw /day
<b>Scenario (professionals)</b>	<b>Decanting phase (12.6 kg)</b> <b>Loading phase: 63 manipulations per day</b> <b>Cleaning phase: 16 manipulations per day</b>		
<b>Loose grains 200g per bait point*</b>			
Tier 1: Without PPE	$1.09 \times 10^{-6}$	$1.1 \times 10^{-6}$	$2.19 \times 10^{-6}$

*\*this assessment covers exposure during use in sachet and at the dose against mice (50g)*

#### **2.7.2.2.2 Exposure of non-professional users**

##### ➤ **Major change application - 2016**

#### **For non-professional users of grain in sachets:**

As a worst case, exposure has been assessed considering FANGA RAT DICAL TECH at the maximum recommended dose of 200 g for the use against rats. This approach also covers human exposure during the control of mice.

Grains being in sachet PE, only exposure during cleaning is considered and therefore, exposure will be the same for treatment against rats and mice.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 4.52 mg/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 5 cleanings for non-professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010).

Therefore, considering 5 cleanings per day, the systemic dose of brodifacoum on fingers/hands during cleaning is  $6.09 \times 10^{-8}$  mg/kg bw/day without any protective equipment.

#### **Total exposure for grains in sachets**

Since grains are in sachets PE, exposure only occurs during cleaning and is estimated at  $6.09 \times 10^{-8}$  mg a.s/kg bw/day without any protective equipment.

*In Annex 5 “Safety for non-professional operators and the general public”, the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out.*

<b>Tier</b>	<b>Inhalation exposure</b>	<b>Dermal exposure</b>	<b>Total exposure</b>
PPE	Systemic dose	Systemic dose	Systemic dose
	mg a.i. / kg bw /day	mg a.i. / kg bw /day	mg a.i. / kg bw /day
<b>Sachet PE (exposure only during cleaning phase)</b>			
Tier 1: Without PPE	na	6.09 x10 <sup>-8</sup>	6.09 x10 <sup>-8</sup>

**2.7.2.3 Indirect exposure as a result of use of the active substance in biocidal product  
Handling of dead rodents (adult, child, infant) – acute scenario**

Exposure can occur during handling of dead rodents by professional and general public. However, this scenario is excluded and considered of low relevance due to unrealistic assumptions (TNsG on human exposure (2007)). Gloves are recommended to help prevent rodent-borne disease, therefore exposure due to this scenario is considered negligible.

**Oral exposure by ingesting bait (infant) – acute scenario**

Besides, exposure of non users can occur during ingestion of poison baits. For the scenario “oral exposure by ingesting bait”, a reverse scenario was calculated. Based on the acute AEL of  $3.3 \times 10^{-6}$  mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 75% (as stated in the Assessment report of brodifacoum), ingestion of more than 1.8 mg of product per day by an infant is needed to exceed the AEL.

**2.7.2.4 Exposure to residues in food**

The intended uses description of the product FANGA RAT-DICAL TECH indicates that these uses are not relevant in terms of residues in food and feed. The product is to be used as rodenticide and does not come in direct or indirect contact with food and feedstuff. No further data are required concerning the residue behaviour.

**2.7.2.5 Combined exposure**

Not relevant.

**2.7.3 Risk assessment for human health**

The estimated exposures for the professional users are compared to the systemic AEL of brodifacoum set in the Assessment Report ( $3.3 \times 10^{-6}$  mg/kg bw/day for short-term and long-term exposures).

**2.7.3.1 Risk for direct exposure**

**2.7.3.1.1 Professional users**

Based on the risk assessment of the active substance, the risk for professional users resulting from the intended use is acceptable for FANGA RAT-DICAL TECH, even if gloves are not worn (%AEL at 5% for the control of rats and mice).

Gloves are anyway recommended to help prevent rodent-borne disease. Moreover, the mention “do not open the sachet” has to be added in the label of the product.

**Table 4: Summary of risk characterisation for professionals for the control of rats and mice**

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
<b>Sachet formulation (exposure during cleaning phase)</b>				
Professionnal (without gloves)	3.3x10 <sup>-6</sup>	1.6x10 <sup>-7</sup>	5	Acceptable

➤ **Major change application - 2016**

The estimated exposures for the professional users are compared to the systemic AEL<sub>long term</sub> of brodifacoum set in the Assessment Report (3,3 x 10<sup>-6</sup> mg a.s/kg bw/day).

Based on the risk assessment of the active substance, the risk for professional users resulting from the intended use is acceptable for loose grains and grains in sachet against rats and mice without PPE.

However, gloves are recommended to help prevent rodent-borne disease.

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
<b>Loose grains (exposure during decanting, loading and cleaning phases)*</b>				
Professional (without PPE)	3.3 x10 <sup>-6</sup>	2.19 x 10 <sup>-6</sup>	66%	Acceptable

*\*this assessment covers exposure during use in sachet and at the dose against mice (50g)*

**2.7.3.1.2 Non-professional users**

➤ **Major change application - 2016**

The estimated exposures for the non-professional users are compared to the systemic AEL<sub>medium term</sub> of brodifacoum set in the Assessment Report (6.7x10<sup>-6</sup> mg a.s/kg bw/day).

Based on the risk assessment of the active substance, the risk for non-professional users resulting from the intended use is acceptable without any personal protective equipment.

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
<b>Sachet PE (exposure only during cleaning phase)</b>				
Non-professional (without PPE)	6.7 x10 <sup>-6</sup>	6.09 x 10 <sup>-8</sup>	1%	acceptable

**2.7.3.2 Risk for indirect exposure**

Based on a reverse scenario, more than 1.8 mg of product per day should be ingested by an infant to exceed the AEL. This indicates that infants are at significant risk of poisoning. Therefore, even if FANGA RAT-DICAL TECH contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children.

Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children and infants.

**2.7.3.3 Risk for consumers via residues**

Considering the intended uses, no dietary risk assessment is necessary.

#### 2.7.3.4 Risk for combined exposure

Not relevant.

#### 2.7.3.5 Conclusion on human health risk assessment

Based on the risk assessment of the active substance, the risk for professional users resulting from the intended use is acceptable for FANGA RAT-DICAL TECH for the control of rats and mice.

Risk of secondary poisoning to infants and children is considered as relevant. Therefore, even if FANGA RAT-DICAL TECH contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children. Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children and infants.

The intended uses description of the product FANGA RAT-DICAL TECH indicates that these uses are not relevant in terms of residues in food and feed. The product is to be used as rodenticide and does not come in direct or indirect contact with food and feedstuff.

#### ***Risk mitigation measures linked to risk assessment for human health***

- Gloves have to be worn to help prevention against rodent-borne disease.
- Do not open the sachets.
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Use in tamper-resistant bait boxes or in covered bait stations.
- Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Covered bait stations must be placed only in areas not accessible to the general public and non-target animals.
- Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Do not place tamper-resistant bait boxes and covered bait stations on surfaces in contact with food, feed or drinks and beverages.
- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
- Remove all bait points after the end of treatment.

#### ***Emergency (information provided in the product Safety Data Sheet)***

- **Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.**
- **Skin contact: Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.**
- **Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.**



- Antidote: vitamin K1 (phytomedione). Contact poison treatment specialist for antidote dosage and INR (or PT) monitoring.
- Keep the container or label available.
- Hazardous to wildlife.

***Disposal considerations***

- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
- Remove all bait points after the end of treatment.

***Required information linked to risk assessment for human health***

None.

***2.7.3.5.1 Summary of risks characterisation of the product for human health***

No unacceptable risk has been observed for professionals using FANGA RAT DICAL TECH supplied as loose grains or grains in sachet without PPE, for the use against rats and, by extension, mice.

No unacceptable risk has been observed for non-professionals using FANGA RAT DICAL TECH supplied in sachets, without PPE, for the use against rats and, by extension, mice.

For the indirect scenario “Infant ingesting bait”, Please refer to the product assessment report related to the biocidal product FANGA RAT DICAL TECH for which an authorisation was granted under Regulation UE 528/2012 by France in 2014

Based on intended uses and proper baiting practices of the biocidal product, contamination of food/feedingstuffs is considered highly unlikely to occur. Brodifacoum baits should not be placed where food, feedingstuffs or drinking water could be contaminated

The risk mitigation measures remain unchanged for non- professional are followed

- Do not open the sachets.
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- For non-professional users, use only in tamper-resistant boxes.
- Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Do not place tamper-resistant bait boxes and covered bait stations on surfaces in contact with food, feed or drinks and beverages.
- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
- Remove all bait points after the end of treatment.

➤ **Renewal application - 2017**

The uses claimed for the renewal are identical to the uses already assessed except the non professional users.

The conclusions made for the professional and non professional users during the first authorization and the major change remain unchanged.

## 2.8 Risk assessment for the environment

### 2.8.1 Fate and distribution in the environment of the active substance brodifacoum

The summary of information about the active substance brodifacoum is carried out with the data from the combined AR of brodifacoum owned by Syngenta Limited and Activa / Pelgar Brodifacoum and Difenacoum Task Force<sup>11</sup>.

#### 2.8.1.1 Degradation

##### 2.8.1.1.1 Abiotic degradation

###### 2.8.1.1.1.1 Hydrolysis in function of pH

Brodifacoum is considered stable to hydrolysis. It was concluded that the hydrolytic half-life ( $DT_{50}$ ) was above one year at environmentally relevant pH. The hydrolytic degradation is deemed negligible.

###### 2.8.1.1.1.2 Photolysis in water

Brodifacoum photolytically degrades in aqueous solution with a half-life ( $DT_{50}$ ) < 1 day. Photolysis of brodifacoum was fast with 38 % of removal in the first hour of exposure. Greater than 89 % of photolysis has occurred by around three hours. No degradation products were detected.

###### 2.8.1.1.1.3 Photolysis in soil

Not relevant for a use inside buildings of products containing Brodifacoum.

###### 2.8.1.1.1.4 Photodegradation in air

The photo-oxidative degradation of brodifacoum in air was estimated by a structural activity relationship (QSAR) method using the Atmospheric Oxidation Program v1.90 (AOPWIN). Brodifacoum is predicted to undergo rapid indirect photolysis with OH radicals and ozone ( $DT_{50}$  = approximately 2 hours). According to TGD the half-life has been recalculated considering  $C_{OH} = 0.5 * 10^6$  molec/cm<sup>3</sup>; corresponding to a  $DT_{50}$  of 0.217 days). There are no predicted effects on the atmosphere.

##### 2.8.1.1.2 Biotic degradation

###### 2.8.1.1.2.1 Aquatic compartment

- Ready biodegradation / inherent biodegradation

Brodifacoum is not readily biodegradable under OECD 301B Test (0% after 28 days). Brodifacoum is not inherently biodegradable under the conditions of the 'Inherent – Concawe Test' (OECD 302D) performed (0% after 56 days).

- Degradation in water/sediment system

No study on water/sediment system of the active substance has been submitted in the combined AR of brodifacoum.

Moreover it is not relevant for a use inside buildings of products containing brodifacoum.

#### 2.8.1.1.2.2 Degradation in STP

No study on water/sediment system of the active substance has been submitted in the combined AR of brodifacoum.

Moreover it is not relevant for a use inside buildings of products containing brodifacoum.

#### 2.8.1.1.2.3 Terrestrial compartment

Brodifacoum is persistent in soil with a  $DT_{50}$  value of 157 days (The Pesticide Manual 13<sup>th</sup> Edition).

Moreover it is not relevant for a use inside buildings of products containing brodifacoum.

#### 2.8.1.2 **Distribution**

Based on literature data, the Koc value (50 000 L/kg, The Pesticide Manual 13<sup>th</sup> Edition) indicates that the active substance would not be mobile in soil and is not expected to contaminate groundwater. A laboratory study carried out by another applicant show that with Koc values which ranged from 17.8 (pH 8.46) to 426 579 (pH 3.29) with a Koc value of 9155 L/kg at pH7.1-7.6, brodifacoum can be considered immobile in soil. Under basic conditions (high pH), Brodifacoum is not likely to be adsorbed onto soils or sewage sludge due to the ionisation of the molecule; whereas under acidic conditions (low pH), Brodifacoum is likely to be adsorbed onto soils or sewage sludge as the molecule is in its neutral or non-ionised form.

Brodifacoum is not expected to move from soil into water.

#### 2.8.1.3 **Accumulation**

Brodifacoum has a log Kow > 6 (6.12) and is highly adsorptive; consequently these properties indicate that brodifacoum is likely to bioaccumulate in aquatic or terrestrial species.

The aquatic BCF has been estimated with calculation method for substances with a  $K_{ow} > 6$ :

$$BCF_{fish} = 35\ 645\ L/kg \text{ (according to Equation 75; TGD).}$$

The terrestrial BCF has been estimated with calculation method:

$$BCF_{earthworm} = 15\ 820\ L/kg \text{ (according to Equation 82d; TGD).}$$

These BCF values confirm the high bioaccumulation of Brodifacoum in aquatic and terrestrial species.

#### 2.8.1.4 **Behaviour in air**

The vapour pressure of brodifacoum has been determined to be  $\ll 1 \times 10^{-6}$  Pa (OECD 104, EC methods A.4). Furthermore, Henry's law constant for brodifacoum has been calculated to be  $\ll 2.18 \times 10^{-3}$  Pa.m<sup>3</sup>.mol<sup>-1</sup> at pH 7 (based on a water solubility of 0.24 mg/L). Based on these data brodifacoum is not expected to partition into atmosphere to a relevant extent.

In addition, brodifacoum is predicted to undergo rapid indirect photolysis with OH radicals and ozone ( $DT_{50}$ = approximately 2 hours) and undergoes rapid direct photodegradation ( $DT_{50}$  = 0.217 days).

## 2.8.2 Effects on environmental organisms for active substance brodifacoum

The summary of information about the active substance brodifacoum is carried out with the data from the combined AR of brodifacoum owned by Syngenta Limited and Activa / Pelgar Brodifacoum and Difenacoum Task Force.

### 2.8.2.1 Aquatic compartment (including water, sediment and STP)

#### 2.8.2.1.1 Aquatic organisms

Based on the results of acute toxicity studies submitted in the combined AR by Activa / PelGar Brodifacoum and Difenacoum Task Force, brodifacoum is very acute toxic to aquatic organisms. No long-term tests have been performed. One study was performed on each of the two trophic levels (daphnia and algae) and two studies were performed on fish. *Selenastrum capricornutum* is the most sensitive species with a 72h E<sub>r</sub>C<sub>50</sub> of 0.04 mg a.s./L.

**Table 5: Toxicity to freshwater aquatic organisms**

Guideline / Test method	Species	Endpoint	Results (mg a.s./L)	Reference
OECD 203	<i>Oncorhynchus mykiss</i> - fish	LC <sub>50</sub> – 96h	0.042	Activa / PelGar Brodifacoum and Difenacoum Task Force CAR a.s. Doc III-A 7.4.1.1
OECD 202	<i>Daphnia magna</i> - invertebrate	EC <sub>50</sub> – 48h	0.25	Activa / PelGar Brodifacoum and Difenacoum Task Force CAR a.s. Doc III-A 7.4.1.2
OECD 201	<i>Selenastrum capricornutum</i> - algae	E <sub>b</sub> C <sub>50</sub> – 72h E <sub>r</sub> C <sub>50</sub> – 72h	0.016 0.04	Activa / PelGar Brodifacoum and Difenacoum Task Force CAR a.s. Doc III-A 7.4.1.3

All Concentrations are expressed on measured concentrations.

Justification of PNEC<sub>water</sub>:

According to the TGD, the PNEC<sub>water</sub> is derived from the 72h E<sub>r</sub>C<sub>50</sub> value (0.04 mg a.s./L) for *Selenastrum capricornutum* divided by an assessment factor of 1000. Therefore,

$$\text{PNEC}_{\text{water}} = 0.04 \mu\text{g a.s./L.}$$

#### 2.8.2.1.2 Sediment dwelling organisms

No experimental data are available for sediment dwelling organisms. A PNEC<sub>sediment</sub> (0.043 mg/kg<sub>wwt</sub>) is derived through the Equilibrium Partitioning Method. However, due to the absence of measured data for the determination of a PEC<sub>sediment</sub> and according to the TGD a quantitative risk characterization

cannot be carried out. Therefore the risk for the sediment compartment will be covered by the risk for the aquatic compartment.

According to the TGD and considering the  $\log K_{ow} > 5$ , the PEC/PNEC ratio for the aquatic compartment is increased by a factor of 10 to take into account the possible additional uptake via sediment ingestion.

**2.8.2.1.3 STP micro-organisms**

The toxicity to microorganisms in a sewage treatment plant (STP) was estimated by a respiration inhibition test (OECD 209) submitted by Activa / PelGar Brodifacoum and Difenacoum Task Force . No effects of Brodifacoum on aerobic biological sewage treatment processes was expected. Due to the lack of measured values of test substance concentration, the EC<sub>10</sub> was conservatively set greater than Brodifacoum' water solubility (0.058 mg a.s/L).

**Table 6: Toxicity to STP microorganisms**

Guideline/Test method	Species / Inoculums	Endpoint / Type of test	Duration	Results [mg a.s/L]				Reference
				EC <sub>10</sub>	EC <sub>20</sub>	EC <sub>50</sub>	EC <sub>80</sub>	
OECD 209	Activated sludge	Respiration Inhibition	3h	> 0.058*				Activa / PelGar Brodifacoum and Difenacoum Task Force CAR a.s. Doc III-A 7.1.4

\* corresponding to the water solubility at pH=7 and T=20°C

Justification of PNEC<sub>microorganisms</sub>:

According to TGD (2003) when an EC<sub>10</sub> from a respiration inhibition test is used an assessment factor of 10 should be applied.

$$PNEC_{STP \text{ microorganisms}} > 0.0058 \text{ mg a.s/L}$$

Additional endpoints:

According to the combined AR of brodifacoum owned by Syngenta Limited and Activa / Pelgar Brodifacoum and Difenacoum Task Force, a lower PNEC value for sewage treatment microorganisms is provided: **PNEC STP microorganisms > 0.0038 mg a.s/L**. Therefore, as the data set are considered equivalent, the worst case PNEC from the combined AR is used in the risk assessment.

**2.8.2.2 Atmosphere**

Brodifacoum has a low volatility and is not intended to be sprayed or fumigated. It is formulated into a non volatile solid consequently its occurrence in air is highly unlikely. Moreover, significant phototransformation in air due to hydroxyl radicals would be expected. Brodifacoum is not expected to contribute to global warming, ozone depletion in the stratosphere, or acidification on the basis of its physical or chemical properties.

**2.8.2.3 Terrestrial compartment**

No effects of brodifacoum, in soil concentration ranging up to 994 mg/kg dw, were found on earthworms in a test conducted according to the guideline OECD 207. LC<sub>50</sub> was determined to be > 994 mg/kg dw, corresponding to a LC<sub>50</sub> >879.6 mg/kg in wet weight.

Table 7: Toxicity to soil organisms

Guideline / Test method	Species	Endpoint / Type of test	Exposure		Results (mg a.s/kg ww soil)		Reference
			design	duration	NOEC	LC <sub>50</sub>	
OECD 207	<i>Eisenia foetida</i>	LC <sub>50</sub>	soil exposure	14days	879.6	>879.6	Activa / PelGar Brodifacoum and Difenacoum Task Force CAR a.s. Doc IIIA 7.5.1.2

Justification of PNEC<sub>soil</sub>:

Since LC<sub>50</sub> was determined to be >879 mg/kg ww, when corrected for soil humidity, an assessment factor of 1000 was used in accordance with TGD (2003).

**PNEC<sub>soil</sub> > 0.88 mg/kg wet weight**

As additional information, brodifacoum-based products are intended for indoor use only, no exposure to soil and groundwater is expected.

#### 2.8.2.4 Non compartment specific effect relevant to the food chain

The exposure of brodifacoum directly to non-target birds and mammals (primary poisoning) and indirectly via target rodent carcasses (secondary poisoning) is considered in the risk assessment.

Table 8: Toxicity to birds and mammals (key studies)

Guideline / Test method	Species	Endpoint / Type of test / Duration	Results		Reference
			NOEC/NO(A)EL	LD <sub>50</sub>	
OPPTS 850.2100	Japanese quail	LD <sub>50</sub> / acute oral Single dose followed by 14 days observation		LD <sub>50</sub> = 19 mg a.s/kg bw	Activa / PelGar Brodifacoum and Difenacoum Task Force CAR a.s. Doc IIIA 7.5.3.1.1
OECD 416	Rat Wistar	High dose F1: haemorrhagic diatheses 2-generation	NO(A)EL Parental (females) = 0.001 mg/kg bw/day		Morris, 1995

#### 2.8.2.4.1 Primary poisoning

##### Acute/short-term qualitative assessment

Acute primary toxicity for birds and mammals is assessed only qualitatively in accordance with the decision from TMIII-06.

**For mammals** the acute toxicity to rat: a LD<sub>50</sub> value =< 5 mg a.s. /kg bw is provided.

Additional endpoints:

According to the combined AR of brodifacoum, a lower LD<sub>50</sub> value of **0.4 mg a.s. /kg bw** is provided by another applicant. Therefore, as the data set are considered equivalent, the worst case LD<sub>50</sub> value from the combined AR is used in the qualitative assessment for comparisons with estimated daily uptakes of brodifacoum (ETE, mg a.s. /kg bw).

**For birds** the acute toxicity to Japanese quail:  $LD_{50} = 19 \text{ mg a.s. /kg bw}$  is provided.

Additional endpoints:

According to the combined AR of brodifacoum, a lower  $LD_{50}$  value of **0.31 mg a.s. /kg bw** is provided by another applicant. Therefore, as the data set are considered equivalent, the worst case  $LD_{50}$  value from the combined AR is used in the qualitative assessment for comparisons with estimated daily uptakes of brodifacoum (ETE, mg a.s. /kg bw).

#### Long-term quantitative assessment

For **mammals**, in a two-generation fertility study with rats, a NOAEL of 0.001 mg/kg bw/day was estimated. According to the TGD, the NOAEL is transformed into a NOEC using a conversion factor of 20, and the  $AF_{\text{oral}}$  of 90 is applied to this NOEC, which results in a

$$PNEC_{\text{oral}} (\text{mammal}) = 0.001/90 = 1.1E-05 \text{ mg/kg bw/day}$$

equivalent to

$$PNEC_{\text{oral}} (\text{mammal}) = 0.001*20/90 = 2.22E-04 \text{ mg/kg food}$$

For **birds** the NOEC for Brodifacoum is based on the results of the chronic toxicity study with Difenacoum (with Japanese Quail), chosen as reference chemical for second generation anticoagulants (NOEC > 0.1 mg Difenacoum /kg diet). An extrapolation factor of 8.05 was applied to correct for differences in toxicity based on the acute test results for Difenacoum ( $LD_{50} = 66 \text{ mg/kg}$ , male and females) and Brodifacoum ( $LD_{50} = 19 \text{ mg/kg bw}$ ), both related to Japanese quail. Brodifacoum results very toxic to birds, with NOEC = 0.012 mg Brodifacoum/kg diet (obtained as NOEC > 0.1 mg Difenacoum /kg diet / 8.05) and NOEL = 0.0012 mg Brodifacoum/kg bw/d.

According to TGD, an assessment factor of 30 is applied to derive the PNEC:

$$PNEC_{\text{oral}} \text{ for birds (dose)} = 0.0012/30 = 4E-05 \text{ mg/ kg bw/ day}$$

equivalent to

$$PNEC_{\text{oral}} \text{ for birds (conc. In food)} = 0.012/30 = 4E-04 \text{ mg/kg food}$$

Additional endpoints: According to the combined AR of brodifacoum, a lower  **$PNEC_{\text{oral}}$  for birds** is provided by another applicant. The long-term toxicity was extrapolated by read across to reproduction toxicity of Difenacoum to Japanese Quail (NOEC > 0.1 mg Difenacoum /kg diet), selected as representative compound of the second generation anticoagulants. A factor of 26 was applied to take into account differences in toxicity between the two compounds, with the brodifacoum more toxic than difenacoum. A NOEC = 0.0038 mg Brodifacoum /kg/ diet and a NOEL = 3.85E-04 mg Brodifacoum/kg bw/d are derived.

According to TGD, an assessment factor of 30 is applied to derive the PNEC:

$$PNEC_{\text{oral}} \text{ for birds (dose)} = 1.3E-05 \text{ mg/ kg bw/ day}$$

equivalent to

$$PNEC_{\text{oral}} \text{ for birds (conc. In food)} = 1.3E-04 \text{ mg/kg food}$$

Therefore, as the data set are considered equivalent, the worst case PNEC from the combined AR is used in the risk assessment.

#### **2.8.2.4.2 Secondary poisoning**



Acute/short-term qualitative assessment

Acute primary toxicity for birds and mammals is assessed only qualitatively in accordance with the decision from TMIII-06.

**For mammals** the acute toxicity to rat:  $LD_{50} = 0.4 \text{ mg a.s. /kg bw}$  recalculated into  **$LC_{50} = 8 \text{ mg/kg food}$** , using the conversion factor bw/dfi of 20 from table 22 in the TGD II is the lowest value for the acute toxicity.

**For birds** a  $LD_{50}$  value of  **$0.72 \text{ mg a.s. /kg food}$**  is provided by another applicant in the combined AR. No data about the dietary toxicity to birds was submitted by Activa / PelGar Brodifacoum and Difenacoum Task Force in the combined AR.

Long-term quantitative assessment

For **mammals**, in a two-generation fertility study with rats, a NOAEL of  $0.001 \text{ mg/kg bw/day}$  was estimated. According to the TGD, the NOAEL is transformed into a NOEC using a conversion factor of 20, and the  $AF_{\text{oral}}$  of 90 is applied to this NOEC, which results in a

$$\text{PNEC}_{\text{oral}} (\text{mammal}) = 0.001 * 20 / 90 = 2.22\text{E-}04 \text{ mg/kg food}$$

equivalent to

$$\text{PNEC}_{\text{oral}} (\text{mammal}) = 0.001 / 90 = 1.1\text{E-}05 \text{ mg/kg bw/day}$$

For **birds** the NOEC for Brodifacoum is based on the results of the chronic toxicity study with Difenacoum (with Japanese Quail), chosen as reference chemical for second generation anticoagulants ( $\text{NOEC} > 0.1 \text{ mg Difenacoum /kg diet}$ ). An extrapolation factor of 8.05 was applied to correct for differences in toxicity based on the acute test results for Difenacoum ( $LD_{50} = 66 \text{ mg/kg}$ , male and females) and Brodifacoum ( $LD_{50} = 19 \text{ mg/kg bw}$ ), both related to Japanese quail. Brodifacoum results very toxic to birds, with  $\text{NOEC} = 0.012 \text{ mg Brodifacoum/kg diet}$  (obtained as  $\text{NOEC} > 0.1 \text{ mg Difenacoum /kg diet} / 8.05$ ) and  $\text{NOEL} = 0.0012 \text{ mg Brodifacoum/kg bw/d}$ .

According to TGD, an assessment factor of 30 is applied to derive the PNEC:

$$\text{PNEC}_{\text{oral}} \text{ for birds (conc. In food)} = 0.012 / 30 = 4\text{E-}04 \text{ mg/kg food}$$

equivalent to

$$\text{PNEC}_{\text{oral}} \text{ for birds (dose)} = 0.0012 / 30 = 4\text{E-}05 \text{ mg/ kg bw/ day}$$

Additional endpoints: according to the combined AR of brodifacoum, a lower  **$\text{PNEC}_{\text{oral}}$  for birds** is provided by another applicant. The long-term toxicity was extrapolated by read across to reproduction toxicity of Difenacoum to Japanese Quail ( $\text{NOEC} > 0.1 \text{ mg Difenacoum /kg diet}$ ), selected as representative compound of the second generation anticoagulants. A factor of 26 was applied to take into account differences in toxicity between the two compounds, with the brodifacoum more toxic than difenacoum. A  $\text{NOEC} = 0.0038 \text{ mg Brodifacoum /kg/ diet}$  and a  $\text{NOEL} = 3.85\text{E-}04 \text{ mg Brodifacoum/kg bw/d}$  are derived.

According to TGD, an assessment factor of 30 is applied to derive the PNEC:

$$\text{PNEC}_{\text{oral}} \text{ for birds (conc. In food)} = 1.3\text{E-}04 \text{ mg/kg food}$$

equivalent to

$$\text{PNEC}_{\text{oral}} \text{ for birds (dose)} = 1.3\text{E-}05 \text{ mg/ kg bw/ day}$$

Therefore, as the data set are considered equivalent, the worst case PNEC from the combined AR is used in the risk assessment.

**2.8.2.5 Summary of PNECs of the active substance Brodifacoum**

**Table 9: Summary of the brodifacoum (a.s.) PNECs used for risk assessment**

Compartment		Test Value	AF	PNEC	Source
Aquatic	PNEC <sub>water</sub>	72h E <sub>r</sub> C <sub>50</sub> = 0.04 mg a.s./L	1000	0.04 µg a.s./L	Combined AR
	PNEC <sub>STP</sub>	EC <sub>10</sub> > 0.0038 mg a.s. /L	100	> 0.0038 mg a.s/L	combined AR
Terrestrial	PNEC <sub>soil</sub>	14-d LC <sub>50</sub> > 879.6 mg a.s. /kg ww soil	1000	> 0.88 mg/kg wet weight	Combined AR
Primary and secondary poisoning	PNEC <sub>coral for birds</sub>	NOEC = 0.0038 mg/kg food NOEL = 3.85E-04 mg/kg bw/day	30	1.3E-04 mg/kg food 1.3E-05 mg/ kg bw/ day	Combined AR
	PNEC <sub>coral for mammals</sub>	NO(A)EL=0.001mg a.s/kg bw/day NOEC=(0.001*20)=0.02 mg a.s/kg food	90	1.1E-05 mg/kg bw/day 2.22E-04 mg/kg food	Combined AR

PNEC values of other applicant of brodifacoum from the combined AR are indicated when they represent worst-case value in comparison with the PNEC values of Activa / PelGar Brodifacoum and Difenacoum Task Force presented in the combined AR. **The lowest PNEC values is used in the risk assessment.**

**2.8.2.6 PBT Assessment**

Persistence

According to results given in the combined AR, brodifacoum is not readily, inherently or anaerobically biodegradable. In addition, Brodifacoum resulted hydrolytically stable, but undergoes rapid photolysis in water. These results indicate according to screening criteria, that brodifacoum can be considered as potentially persistent (P) very persistent (vP).

Bioaccumulation

Based on log Kow = 6.12 and BCF<sub>fish</sub> = 35 645 L.Kg<sup>-1</sup> (according to Equation 75; TGD), brodifacoum potentially fulfils the B criterion and vB criterion.

Toxicity

Brodifacoum is proposed to be classified as T+; R/27/28, T; R48/24/25, N; R50/53. According to the TGD, brodifacoum fulfils the T criterion.

**Brodifacoum is considered a potential PBT, according to the TGD on Risk Assessment (2003).**

**2.8.3 Effects on environmental organisms for biocidal product**

It is important to notice that the applicant did not provide ecotoxicological data about the biocidal product FANGA RAT-DICAL TECH. Consequently, all the effects assessment is based on the data obtained from the active substance brodifacoum (Combined Assessment Report According to Directive 98/8EC, Active substance in Biocidal Products, Brodifacoum CAS 56073-10-0, Product Type 14 (Rodenticides), RMS Italy, Revision 2: November 2010).

Denatonium benzoate is used in the biocidal product as bittering agent. This substance is classified as “Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment” in

the frame of the Directive 91/414/EEC. Nevertheless at the concentration used in FANGA RAT-DICAL TECH, the substance does not contribute to the classification of the biocidal product.

No other substance used in the biocidal product is classified for the environment.

Therefore, considering that the product contains no substances of concern except brodifacoum, environmental effects following the use of FANGA RAT DICAL TECH can be extrapolated from the environmental effects of the active substance brodifacoum only.

### **2.8.3.1 Aquatic compartment (including water, sediment and STP)**

#### **2.8.3.1.1 Aquatic organisms**

Refers to section 2.8.2.1.

#### **2.8.3.1.2 Sediment dwelling organisms**

Refers to section 2.8.2.1

#### **2.8.3.1.3 STP micro-organisms**

Refers to section 2.8.2.1.

### **2.8.3.2 Atmosphere**

Refers to section 2.8.2.2.

### **2.8.3.3 Terrestrial compartment**

Refers to section 2.8.2.3.

### **2.8.3.4 Non compartment specific effect relevant to the food chain**

Refers to section 2.8.2.4.

### **2.8.3.5 Summary of PNECs**

Refers to section 2.8.2.5.

## **2.8.4 Environmental exposure assessment**

As the product contains no substances of concern except brodifacoum, it is considered that risks posed to environment following the use of the product FANGA RAT-DICAL TECH can adequately be assessed based on the evaluation conducted for the active substance. Therefore the exposure assessment is carried out with the data obtained from the active substance brodifacoum only.

The product FANGA RAT-DICAL TECH is a ready-to-use rodenticidal bait containing 0.005% brodifacoum (0.025 g/kg). The product is in the form of cereal grains supplied in sachet for professional users. The product is used at 50 g for mouse and 200 g for rat / bait point. According to the applicant, the sachets containing impregnated grains are placed in secured bait stations, inside domestic,

industrial, and farm buildings. The secured bait points are refilled 4 times over 28 days. Dead rodents and unconsumed baits are removed each week.

As the product is applied indoor only, no environmental compartment is exposed to FANGA RAT-DICAL TECH. Nevertheless primary and secondary poisoning cannot be excluded. Indeed, pets living in treated buildings could be exposed directly to the product. Moreover even if the product is applied inside buildings, rats can live some days before dying. Therefore, they have the time to escape outside buildings and to be eaten by predators.

➤ **Major change application - 2016**

The product FANGA RAT DICAL TECH is a rodenticide bait containing 0.0025% brodifacoum (0.025 g/kg). The product is in the form of grains. The applicant intends manual applications of baits in bait stations for non-professional and professional users. The product is used as 40 g for mouse and 200 g for rat / bait point. The secured bait points are refilled 4 times over 28 days. Dead rodents and unconsumed baits are removed each week.

FANGA RAT DICAL TECH is used in the following areas:

- In and around buildings (professional and non-professional use);
- Open areas (professional and non-professional use);
- Waste dumps area (professional use only).

The use in sewers was also required by the applicant. However, according to the grain formulation of the product, the use was considered not relevant (*cf.* efficacy part).

For the intended uses, the terrestrial (including groundwater) compartment is the only relevant compartment of release. The risks are also calculated for primary and secondary poisoning.

**2.8.4.1 Aquatic compartment (surface water, sediment, STP)**

Exposure of the aquatic compartment *via* the STP after the treatment with rodenticides is only relevant for indoor application of liquid poisons, residues from mixing and cleaning (ESD PT14). As FANGA RAT-DICAL TECH is a solid form and is intended to be used indoor only, indirect or direct exposure of the aquatic compartment may be considered negligible.

➤ **Major change application - 2016**

Exposure of the aquatic compartment *via* the STP after the treatment with rodenticides is only relevant for sewers. Contamination of surface water, STP or sediment with brodifacoum from the placing of bait in and around buildings, in open areas or in waste dumps is considered negligible according to the ESD PT14.

**2.8.4.2 Atmospheric compartment**

Due to its physico-chemical properties (low vapour pressure of  $2.6 \times 10^{-22}$  Pa at 20°C and low Henry's law constant of  $2.35 \times 10^{-18}$  Pa.m<sup>3</sup>.mol<sup>-1</sup>), brodifacoum is not expected to be present in the atmosphere in significant quantities. The exposure of air is therefore considered negligible for the application of FANGA RAT-DICAL TECH biocidal product.

➤ **Major change application - 2016**

Due to its physico-chemical properties (low vapour pressure  $\ll 1 \times 10^{-6}$  Pa and low Henry's law constant  $\ll 2.18 \times 10^{-3}$  Pa.m<sup>3</sup>.mol<sup>-1</sup>), brodifacoum is not expected to be present in the atmosphere in significant quantities. The exposure of air is therefore considered negligible for the application of FANGA RAT DICAL TECH biocidal product.

**2.8.4.3 Terrestrial compartment (soil and groundwater)**

As FANGA RAT-DICAL TECH is intended to be used indoor only, no exposure to soil and groundwater is expected.

➤ **Major change application - 2016**

**2.8.4.3.1 In and around buildings**

The exposure assessment has been carried out according to the ESD (Larsen, 2003) for rodenticides (ESD PT14)<sup>12</sup> and the GBPR IV Part B<sup>13</sup>. The ESD PT14 indicates that the only primary compartment to be exposed during a use in and around buildings is the terrestrial compartment. Emission calculations to soil and groundwater were conducted with the default parameters of the ESD PT14 as well as the specific information on the product provided by the applicant:

- A brodifacoum concentration of 0.0025% (w/w),
- The protection of baits in bait stations,
- Maximal dose rates: 200 g for rats and 40 g for mice,
- Minimal distance between two bait points: 5 m for rats and 1 m for mice,
- Number of refilling times: 5 (default value) / 1.5 (refined parameter).

Exposure of the terrestrial compartment (soil) will occur when brodifacoum bait is deployed outdoors. ESD (Larsen, 2003) considers a scenario that entails outdoor baiting with bait grains around a farm building. In this situation, exposure is assumed to arise through a combination of transfer (direct release) and deposition *via* urine and faeces (disperse release) onto soil. The active substance metabolism is taken into account; ESD (Larsen, 2003) considers that, in general, 90% of the total amount of rodenticide consumed by the target rodents over the duration of the outdoor baiting campaign enters soil via urine and faeces.

According to the ESD PT14 and the applicant's usage, the normal campaign baiting is:

- Day 1: Treatment with one normal bait per box ,
- Day 3: 100 % replenishment,
- Day 7: 25-50 % replenishment,
- Day 14: 10 % replenishment,
- Day 21: 0% replenishment

The normal campaign baiting is roughly equivalent to 1.5 replenishments corresponding to a total direct release over 28 days.

In both scenarios, the direct and disperse brodifacoum releases ( $E_{local,soil}$ ) to the relevant soil surfaces may be calculated according to the input values presented in the table below. The different PEC values are calculated using the GBPR equations. The degradation in soil was not considered in the calculations.

**Table 2-10 PEC brodifacoum in soil and groundwater for uses in and around buildings**

Symbol	Variable/parameters	ESD parameters: worst-case		Default realistic		Refined and specific parameters: typical scenario		Unit
		Rat	Mouse	Rat	Mouse	Rat	Mouse	
<b>INPUTS</b>								

<sup>12</sup> EUBEES 2 - Emission scenario document for biocides used as rodenticides (Larsen, 2003)

<sup>13</sup> Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment (active substances), Version 1.0, April 2015

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$Q_{prod}$ :	Amount of product used in control operation for each bait box	200	40	200	40	[g]
$F_{Cproduct}$ :	Concentration of active substance in product	0.025	0.025	0.025	0.025	[g.kg <sup>-1</sup> ]
Nsites:	Number of application sites	10	10	10	10	[-]
$N_{refil}$ :	Number of refilling times	5	5	1.5	1.5	[-]
$F_{release-D, soil}$ :	Fraction of product released directly to soil	0.01	0.01	0.01	0.01	[-]
$F_{release-ID, soil}$ :	Fraction released indirectly to soil	0.9	0.9	0.9	0.9	[-]
$K_{oc}$	Organic carbon adsorption coefficient	9 155	9 155	9 155	9 155	[L.kg <sup>-1</sup> ]
Distance	Distance between 2 bait points	5	1	5	1	[m]
$AREA_{exposed-D}$ :	Area directly exposed to rodenticide originating from one bait box	0.09	0.09	0.09	0.09	[m <sup>2</sup> ]
$AREA_{exposed-ID}$ :	Area indirectly exposed to rodenticide	550	110	550	110	[m <sup>2</sup> ]
$DEPTH_{soil}$ :	Depth of exposed soil	0.1	0.1	0.1	0.1	[m]
$RHO_{soil}$ :	Density of exposed soil	1700	1700	1700	1700	[kg.m <sup>-3</sup> ]
<b>OUTPUTS</b>						
$E_{local-soil-campaign, direct}$ :	<i>Direct emission to soil from a campaign</i>	2.50E-03	5.00E-04	7.50E-04	1.50E-04	[g.camp <sup>-1</sup> ]
$E_{local-soil-campaign, indirect}$ :	<i>Indirect emission to soil from a campaign</i>	2.23E-01	4.46E-02	6.68E-02	1.34E-02	[g.camp <sup>-1</sup> ]
$E_{local-soil-campaign}$ :	<i>Total emission to soil from a campaign</i>	2.25E-01	4.51E-02	6.76E-02	1.35E-02	[g.camp <sup>-1</sup> ]
$C_{local-soil-D}$	<i>Local concentration in soil due to direct release (<math>AREA_{exposed-D}</math>) after a campaign:</i>	1.63E-02	3.27E-03	4.90E-03	9.80E-04	[mg.kg <sup>-1</sup> <sub>wwt</sub> ]
$C_{local-soil-ID}$	<i>Concentration in soil due to indirect (disperse=<math>AREA_{exposed-ID}</math>) release after a campaign:</i>	2.38E-03	2.38E-03	7.15E-04	7.15E-04	[mg.kg <sup>-1</sup> <sub>wwt</sub> ]
$C_{local-soil}$	<b><i>Worst case total concentration in soil = <math>C_{local-soil-D}</math> + <math>C_{local-soil-ID}</math> = <math>PEC_{soil}</math></i></b>	<b>1.87E-02</b>	<b>5.65E-03</b>	<b>5.62E-03</b>	<b>1.70E-03</b>	<b>[mg.kg<sup>-1</sup><sub>wwt</sub>]</b>

$C_{local\ soil\ mean\ concentration}$	<i>Mean concentration in soil. The total amount of product release (=E<sub>local soil-campaign</sub>) is divided by the whole area exposed(=AREA<sub>exposed-ID</sub>)</i>	2.41E-03	2.41E-03	7.23E-04	7.23E-04	[mg.kg <sup>-1</sup> <sub>wwt</sub> ]
$K_{p\ soil}$	<i>Partition coefficient solid-water in soil</i>	183	183	183	183	[L.kg <sup>-1</sup> ]
$K_{soil\ water}$	<i>Soil-water partitioning coefficient</i>	275	275	275	275	[m <sup>3</sup> .m <sup>-3</sup> ]
$PEC_{local\ soil,\ porew}$	<i>Worst case concentration in groundwater (based on the total concentration in soil)</i>	1.16E-04	3.49E-05	3.47E-05	1.05E-05	[mg.L <sup>-1</sup> ]
$PEC_{local\ soil,\ porew}$	<i>Mean concentration in groundwater (based on mean concentration in soil)</i>	1.49E-05	1.49E-05	4.47E-06	4.47E-06	[mg.L <sup>-1</sup> ]

#### 2.8.4.3.2 Open areas

FANGA RAT DICAL TECH is applied in open areas inside or near the openings of the tunnels of the target rodents. According to the ESD (Larsen, 2003), the use near the openings of the tunnels is covered by the assessment of the scenario “in and around buildings” with bait box. Thus this section “Open areas” only assesses the use inside the tunnels during which, according to the scenario presented in ESD (Larsen, 2003), two treatments would typically be applied in the interval of six days. Bait deployment comprises 200 g of product against rats and 40 g against mice per application and per tunnel entrance. Based on a tunnel of 8 cm diameter, worst-case soil exposure is assumed to occur to a depth of 10 cm from the contact half (*i.e.* the burrow floor) of a 30 cm tunnel section in which the bait is placed. This section of tunnel floor is assumed to receive an input corresponding to 5% of the product during application and a further 20% as the bait is consumed.

Considering the localized treated area, the risk for groundwater from this use was not considered relevant.

**Table 2-11 PEC of brodifacoum in soil and groundwater for uses in open area**

			Rat treatment	Mice treatment	unit
INPUTS	$Q_{prod}$ :	Amount of product used in control operation	200	40	[g.burrow <sup>-1</sup> ]
	$F_{C\ product}$ :	Fraction of active substance in product	0.025	0.025	[g a.i. kg <sup>-1</sup> ]
	$N_{app}$ :	Number of application sites	1	1	[-]
	$N_{refil}$ :	Number of refilling times	2	2	[-]
	$F_{release,\ soil,\ appl}$ :	Fraction of product released to soil during application	0.05	0.05	[-]
	$F_{release,\ soil,\ use}$ :	Fraction of product released to soil during use	0.2	0.2	[-]

	$V_{soil\,exposed}$ :	Soil volume exposed to rodenticide	0.0085	0.0085	[m <sup>3</sup> ]
	$RHO_{soil}$ :	Density of wet exposed soil	1700	1700	[kg.m <sup>-3</sup> ]
	Koc	Organic carbon adsorption coefficient	9155	9155	[L.kg <sup>-1</sup> ]
OUTPUTS	$E_{local\,soil-campaign}$	<i>Local emission of active substance to soil during a campaign</i>	2.50E-03	5.00E-04	[g.camp]
	$C_{local\,soil}$	<i>Local concentration in soil after a campaign</i>	1.73E-01	3.46E-02	[mg.kg <sup>-1</sup> <sub>wwt</sub> ]

### 2.8.4.3.3 Waste dumps

The default exposure scenario suggests in the event of an infestation outbreak a treatment with 40 kg of baits distributed over an area of 1 ha, with a total of seven applications per year. In this situation, soil exposure is assumed to arise through a combination of deposition via urine and faeces combined with rodenticide contained in the carcasses of poisoned target rodents. In general, ninety percent of the total amount of rodenticide consumed by the target rodents over the duration of each baiting campaign is assumed to enter soil over the 1 ha surface.

FANGA RAT DICAL TECH is intended to be used in bait stations containing 200 g of biocidal product (0.0025%) with 5 m spacing. So to predict the concentration of brodifacoum in soil and groundwater for the uses in waste dump, the intended doses are calculated for the 1 ha surface as below:

$Q_{prod} = (\text{length of the waste dump of 1ha/distance between bait} + 1) \times (\text{length of the waste dump of 1ha/distance between bait}) \times (\text{amount of product per bait point})$

$Q_{prod} = ((100 \text{ m} / 5 \text{ m}) + 1) \times (100 \text{ m} / 5 \text{ m}) \times 0.20 \text{ kg}_{product}$

$Q_{prod} = 84 \text{ kg/ha}$

The ESD (Larsen, 2003) considers that, in general, 90% of the total amount of rodenticide consumed by the target rodents over the duration of the outdoor baiting campaign enters soil via urine and faeces.

**Table 2-12 PEC of brodifacoum in soil and groundwater for uses in waste dump**

			Anticoagulant-Rat- ESD default values	Dose for rat intended by the applicant	Unit
INPUT	$Q_{prod}$	Amount of product used in control operation / ha	40	84	[kg.ha <sup>-1</sup> ]
	$FC_{product}$	Fraction of active substance in product	0.025	0.025	[g a.i.kg <sup>-1</sup> ]
	$N_{app}$	Number of applications	7	7	[-]
	$F_{release, soil}$	Fraction of product released to soil	0.9	0.9	[-]
	$AREA_{exposed}$	Area exposed to rodenticide	10 000	10 000	[m <sup>2</sup> ]
	$DEPTH_{soil}$	Depth of exposed soil	0.1	0.1	[m]
	$RHO_{soil}$	Density of wet exposed soil	1700	1700	[kg.m <sup>-3</sup> ]
	$Koc$	Organic carbon adsorption coefficient	9 155	9 155	[L.kg <sup>-1</sup> ]



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<b>OUTPUT</b>	<b>Elocal<sub>soil-campaign</sub></b>	<i>Local emission of active substance to soil from a campaign</i>	6.3	13.2	[g.camp <sup>-1</sup> ]
	<b>Clocal<sub>soil</sub></b>	<i>Local concentration in soil after a campaign</i>	0.0037	0.0078	[mg.kg <sup>-1</sup> <sub>wwt</sub> ]
	<b>Kp<sub>soil</sub></b>	<i>Partition coefficient solid-water in soil</i>	1.83E+02	1.83E+02	[L.kg <sup>-1</sup> ]
	<b>K<sub>soil water</sub></b>	<i>Soil-water partitioning coefficient</i>	2.75E+02	2.75E+02	[m <sup>3</sup> .m <sup>-3</sup> ]
	<b>PEClocal<sub>soil, porew</sub></b>	<i>Concentration in groundwater</i>	2.29E-05	4.81E-05	[mg.L <sup>-1</sup> ]

**2.8.4.4 Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)**

**2.8.4.4.1 Primary poisoning**

As stated in the ESD (Larsen, 2003), primary poisoning hazard to mammals and birds (both wild and domestic) can be considered small when rodenticides are applied according to the label instructions. In the scenario “in and around buildings” when the product is placed in protected bait point, the risk for primary poisoning is mainly for birds and mammals of equal size or smaller as the target rodents, which may be able to enter into the bait stations. Another exposure of non-target animals may arise when target rodents carry bait away from bait stations.

Worst case exposure estimations are based on the equations and default values proposed by the ESD (Larsen, 2003). Some defaults parameters may be replaced by product-specific properties.

➤ **Major change application - 2016**

Non-target birds and mammals may encounter bait containing brodifacoum if they are small enough to be able to reach the bait, or because the bait is inadequately safeguarded or a secured bait point has become damaged, or by finding pieces of bait which have been removed by target rodents. The quantities of brodifacoum potentially accessible to non-target mammals can be calculated based on the size and number of bait at each secured bait point and an estimate of the amount of bait removed from them. The primary poisoning risk assessment is presented in this dossier according to the scenario “in and around building” covering the other uses.

2.8.4.4.1.1 Primary poisoning – Tier 1 assessment

The Tier 1 assessment assumes that the whole day’s food requirement is satisfied by consumption of baits and therefore the concentration in food will be the same as the concentration of the active substance in the bait: 25 mg.kg<sup>-1</sup> (0.0025% w/w of brodifacoum in FANGA RAT-DICAL TECH).

Hence, **the worst case Tier 1 PEC<sub>oral</sub> is 25 mg.kg<sup>-1</sup>.**

➤ **Major change application - 2016**

**For birds**, a separate, graded assessment of long-term risks of primary poisoning by bait has been done. It is based on different intakes of brodifacoum-treated bait in relation to untreated food, depending on to which extent brodifacoum bait is accessible to birds.

**Table 2-13 PEC<sub>oral</sub> for non-target, birds exposed to brodifacoum in bait removed from secured bait points in and around buildings**

Proportion of bait point contents accessible, expressed as fraction of ingested food (%)	Brodifacoum conc. potentially ingested by non-target vertebrates (mg/kg) ≡ PEC <sub>oral</sub>
100	25
50	12.5
40	10
30	7.5
20	5
10	2.5
5	1.25
2	0.5
1	0.25

2.8.4.4.1.2 Primary poisoning – Tier 2 assessment, acute exposure

According to ESD (Larsen, 2003), a Tier 2 assessment can be done estimating a daily uptake of a compound (ETE, mg.kg<sup>-1</sup>.bw.d<sup>-1</sup>) by non-target animals according to the equation 19 of ESD:

$$ETE = (FIR/BW) * C * AV * PT * PD \text{ (mg brodifacoum /kg bw/day)}$$

With:

ETE is the estimated daily uptake of the active substance (mg.kg<sup>-1</sup>.bw.d<sup>-1</sup>),

FIR: food intake rate of the indicator species (g.d<sup>-1</sup>),

BW: indicator species body weight (g),

C: concentration of the active substance in fresh diet (mg.kg<sup>-1</sup>),

AV: avoidance factor (-),

PT: fraction of diet obtained in treated area (-),

PD: the fraction of the food type in the diet (-).

In Tier 2 Step 1 (worst case) AV, PT and PD are all set at 1. In Step 2 (realistic worst case) AV and PT are refined to 0.9 and 0.8, respectively.

**Table 14: Expected concentrations of brodifacoum in non-target animals in the worst case (Step 1) and realistic worst case (Step 2) for acute situations.**

Non-target animal	BW (g) <sup>a</sup>	FIR (g dry weight.day <sup>-1</sup> )	C (mg.kg <sup>-1</sup> )	ETE = concentration of brodifacoum after one meal (mg.kg <sup>-1</sup> bw.d <sup>-1</sup> )	
				Step 1	Step 2
<b>Dog</b>	10 000	456 <sup>b</sup>	25	1.14	0.82
<b>Pig</b>	80 000	600 <sup>a</sup>	25	0.19	0.14
<b>Pig young</b>	25 000	600 <sup>a</sup>	25	0.60	0.43
<b>Tree sparrow</b>	22	7.6 <sup>a</sup>	25	8.64	6.22
<b>Chaffinch</b>	21.4	6.42 <sup>a</sup>	25	7.50	5.40
<b>Wood pigeon</b>	490	53.1 <sup>a</sup>	25	2.71	1.95
<b>Pheasant</b>	953	102.7 <sup>a</sup>	25	2.70	1.94

<sup>a</sup> From EUBEES 2, Table 3.1, section 3.2.1

<sup>b</sup> From EUBEES 2, using the equation  $\log FIR = 0.822 \log BW - 0.629$  (for mammals)

2.8.4.4.1.3 Primary poisoning – Tier 2 assessment, long-term exposure

The long-term risks of brodifacoum are determined by the expected concentrations (EC) in the animal after metabolism and elimination, which is regarded as PEC. The EC values are calculated on the basis of the actual dose of the substance consumed by a non-target animal each day (ETE) using the realistic worst case scenario (Step 2), calculated above. Calculations are performed according to the equation 20 of the ESD.

$$EC = ETE \times (1 - El)$$

According to the ESD, a default value of 0.3 for daily uptake eliminated (EI) can be used if no studies are submitted. The EC values are the expected concentrations of active substance brodifacoum in non-target animals in primary poisoning scenarios after one meal followed by a 24 hour elimination period.

**Table 15: Expected concentrations of brodifacoum in non-target animals in realistic worst case (Step 2) for long-term situation.**

Non-target animal	EC, conc. of brodifacoum after one day of elimination (mg.kg <sup>-1</sup> bw)
	<b>Step 2</b>
<b>Dog</b>	0.57
<b>Pig</b>	0.09
<b>Pig young</b>	0.30
<b>Tree sparrow</b>	4.35
<b>Chaffinch</b>	3.78
<b>Wood pigeon</b>	1.37
<b>Pheasant</b>	1.36

**2.8.4.4.2 Secondary poisoning**

**Secondary poisoning via the aquatic food chain**

As no exposure of the aquatic compartment is foreseen with the use of FANGA RAT-DICAL TECH inside buildings, no risk assessment for secondary poisoning through the aquatic food chain is required.

**Secondary poisoning via the terrestrial food chain**

As no exposure of the terrestrial compartment is foreseen with the use of FANGA RAT-DICAL TECH inside buildings, no risk assessment for secondary poisoning through the terrestrial food chain is needed.

➤ **Major change application - 2016**

According to the GBPR secondary poisoning through the terrestrial route is soil → terrestrial organisms (earthworm) → earthworm-eating mammal or bird. Since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the amount of substance that is in the soil. The risk assessment for secondary poisoning for earthworm-eating mammals and birds has been carried out for the in and around use and for the waste dump application. As the use in open area is quite localised, the exposure of earthworm was deemed negligible in this case.

The calculation is done according to equation 80 and 82 (GBPR, 2015):

**PEC oral, predator = C<sub>earthworm</sub>**

**C<sub>earthworm</sub> = (BCF<sub>earthworm</sub> \* C<sub>porewater</sub>) + C<sub>local soil mean concentration</sub> \* F<sub>gut</sub> \* CONV<sub>soil</sub>) / (1+F<sub>gut</sub> \* CONV<sub>soil</sub>)**

With (example for rat treatment application for the in and around - typical scenario):

BCF<sub>earthworm</sub> (bioconcentration factor for earthworms on wet weight basis) = **15 820** L.kg<sub>wet earthworm</sub><sup>-1</sup>.

C<sub>porewater</sub> (concentration in pore water) = **4.47 E-06** mg.L<sup>-1</sup>, based on mean concentration in soil– typical case.

$C_{\text{local soil mean concentration}}$  (concentration in soil) = **7.23 E-04** mg.kg<sup>-1</sup><sub>wwt</sub>, based on mean concentration in soil– typical case.

$F_{\text{gut}}$  (fraction of gut loading in worm. default value) = 0.1 Kg<sub>dwt</sub>.kg<sup>-1</sup><sub>wwt</sub>.

$CONV_{\text{soil}}$  (conversion factor for soil concentration wet-dry weight soil) = 1.13 kg<sub>wwt</sub>.kg<sup>-1</sup><sub>dwt</sub>.

According to the GBPR, the most appropriate scenario is that 50% of the diet comes from a local area and 50% comes from the regional area. Thus when the  $PEC_{\text{local soil}}$  is used in calculation, the  $PEC_{\text{oral predator}}$  to be used in risk assessment is  $C_{\text{earthworm}} \times 0.5$ .

**Table 2-16 Expected concentrations of brodifacoum in predator**

	PEC oral, predator mg/kg <sub>wet earthworm</sub> <sup>-1</sup>	
	ESD Default parameters: realistic worst-case	Refined and specific parameters: typical scenario
<b>TIER I: Worst case (based on the total concentration in soil)</b>		
Rat treatment	8.24E-01	2.47E-01
Mice treatment	2.47E-01	7.46E-02
<b>TIER I: Mean (based on the mean concentration in soil)</b>		
Rat treatment	1.06E-01	3.18E-02
Mice treatment	1.06E-01	3.18E-02
<b>TIER II: Mean (based on the mean concentration in soil) + considering degradation in soil (two over 180 d with DT50 soil=298)</b>		
Rat treatment	1.02E-01	3.07E-02
Mice treatment	1.02E-01	3.07E-02

**Secondary poisoning for the rodent-eating mammal or the rodent-eating bird**

According to the ESD (Larsen, 2003) document, for uses ‘in and around buildings’ it is assumed that predators among mammals and birds may occur inside buildings or they may hunt rats in the immediate vicinity of buildings (parks and gardens or further away). Scavengers may also search for food close to buildings.

Therefore secondary poisoning through poisoned rats exists, even in case of an indoor use. Secondary poisoning hazard can only be ruled out completely when the rodenticide is used in fully enclosed spaces so that rodents cannot move to outdoor areas or to (parts of) buildings where predators may have access.

2.8.4.4.2.1 Secondary poisoning - Tier 1 assessment, acute

Calculations of the risk for secondary poisoning of scavengers and predators are done by determining the concentration of brodifacoum in their food, i.e. the poisoned rodents. This  $PEC_{\text{oral}}$  is then compared to the  $LC_{50}$  values for a qualitative risk assessment in accordance with the decision from TM III-06. According to the ESD section 3.3.1, the consumption of rodenticides makes up at least 20 % of total consumptions in a choice test and could in a worst case be up to 100 %, whilst 50 % would be considered as the normal situation. Therefore, in the calculations the fractions of the food type in the diet (PD) are set to 0.2, 0.5 and 1.0. The FIR/BW quotient (food intake rate of the indicator species/indicator species body weight) is a default value set to 0.1, i.e. it is assumed that the rats eat 10 % of their bodyweight each day. The avoidance factor (AV) and the fraction of diet (PT) obtained in the area are both set to 1.

The calculations are done according to equation 19 in the ESD:

$$ETE = (FIR/BW) \times C \times AV \times PT \times PD \text{ (mg.kg}^{-1}\text{.d}^{-1}\text{)}$$

This equation gives the concentration of brodifacoum in rodent ( $PEC_{oral}$ ) after the first meal. Considering the elimination rate and the mean time to death (seven days), the concentrations in rodents can be calculated each day by the equation 21 in the ESD:

$$EC_n = \sum_{n-1} ETE \times (1 - EI)^n$$

For the active substance brodifacoum, the default value of 0.3 is used for elimination (EI).

**Table 17: Residues of brodifacoum in target animals at specific points in time and varying bait consumption**

	Residues in target animal (mg.kg <sup>-1</sup> bw)		
	20%	50%	100%
<b>Day 1 after the first meal</b>	0.5	1.3	2.5
<b>Day 2 before new meal</b>	0.4	0.9	1.8
<b>Day 5 after the last meal</b>	1.4	3.5	7
<b>Day 7 mean time to death</b>	0.7	1.7	3.4

According to the ESD, the concentrations of brodifacoum in rats are at peak after consuming bait during 5 days; thereafter the concentrations in rodents are decreasing until day 7 due to excretion and metabolism of the rodenticide in rodents. The values from day 5 (after the meal) are used as worst case  $PEC_{oral}$ .

2.8.4.4.2.2 Secondary poisoning - Tier 1 assessment, long-term

To assess the risk of long-term secondary poisoning to mammals, the PEC in rodents after 1 day and after 5 days are used considering that the consumption of rodenticides makes up 100% of total consumptions (refer to Table 17).

**Table 18: Residues of brodifacoum in target animals at specific points in time and varying bait consumption used in the long term assessment**

	$PEC_{oral}$ Brodifacoum conc. in target rodent (mg.kg <sup>-1</sup> bw), ESD default values
<b>Birds</b>	7
<b>Mammals</b>	7

➤ **Major change application - 2016**

To assess the risk of long-term secondary poisoning, the PEC in rodents after 5 days are used considering that the consumption of rodenticides makes up 100% of total consumptions (refer to Table above).

**Table 2-19 Residues of brodifacoum in target animals at specific point in times and varying bait consumption used in the long term assessment**

Birds / Mammals	$PEC_{oral}$ Brodifacoum conc. in target rodent (mg.kg <sup>-1</sup> bw). ESD default values
<b>Day 5 after the last meal</b>	6.95

2.8.4.4.2.3 Secondary poisoning - Tier 2 assessment, long-term

For the Tier 2 assessment, the average food intake for each species and the average weight of the species have been considered, according to the Table 3.5 in the ESD. The calculations are based on the expected values for uptake of active substance by a mammal predator after a single day of exposure presented as an illustrative example in the ESD.

The amount of a.i. consumed by the non-target animal is 7 mg.kg<sup>-1</sup> bw for rodents caught on day 5 and 8.3 mg.kg<sup>-1</sup> bw for resistant rodents caught on day 14, also assuming that the non-target animals feed to 50 % on the rodents, all in accordance with the ESD. By knowing the amount of a.i. consumed by the non-target animal and the weight of the animal, the PEC (concentration in non-target animal) after one day consumption of rodents can be calculated. The results are presented in Table 20.

**Table 20: Expected concentrations of brodifacoum in non-target animals (predators/carnivores) due to secondary poisoning after a single day of exposure (concentration of brodifacoum in rodenticide bait 0.0025%). Rodents fed 100% on rodenticide and predators/carnivores fed 50% on poisoned rodents.**

Species	Body weight (g)	Daily mean food intake (g.d <sup>-1</sup> )	Normal susceptible rodents caught on day 5		Resistant rodents caught on day 14	
			Amount a.i. (mg) <sup>1</sup>	Conc. (mg.kg <sup>-1</sup> ) <sup>2</sup>	Amount a.i. (mg) <sup>1</sup>	Conc. (mg.kg <sup>-1</sup> ) <sup>2</sup>
<b>Barn owl</b> <i>(Tyto alba)</i>	295	72.9	0.26	0.85	0.3	1.05
<b>Kestrel</b> <i>(Falco tinnunculus)</i>	209	78.7	0.28	1.3	0.33	1.55
<b>Little owl</b> <i>(Athene noctua)</i>	164	46.4	0.16	1.0	0.19	1.15
<b>Tawny owl</b> <i>(Strix aluco)</i>	426	97.1	0.34	0.8	0.4	0.95
<b>Fox</b> <i>(Vulpes vulpes)</i>	5700	520.2	1.8	0.3	2.16	0.4
<b>Polecat</b> <i>(Mustela putorius)</i>	689	130.9	0.46	0.65	0.54	0.8
<b>Stoat</b> <i>(Mustela erminea)</i>	205	55.7	0.2	0.95	0.23	1.15
<b>Weasel</b> <i>(Mustela nivalis)</i>	63	24.7	0.09	1.35	0.1	1.65

<sup>1</sup> Amount a.i. consumed by non-target animal

<sup>2</sup> Conc. in non-target animal

➤ **Major change application - 2016**

For the Tier 2 assessment the average food intake for each species and the average weight of the species have been considered, according to the Table 3.5 in the ESD. The calculations are based on the expected values for uptake of active substance by a mammal predator after a single day of exposure presented as an illustrative example in the ESD.

The amount of a.i. consumed by the non-target animal is 6.95 mg.kg<sup>-1</sup> bw for rodents caught on day 5 and 8.3 mg.kg<sup>-1</sup> bw for rodents caught on day 14, also assuming that the non-target animals feed to

50 % on the rodents, all in accordance with the ESD. By knowing the amount of a.i. consumed by the non-target animal and the weight of the animal, the PEC (concentration in non-target animal) after one day consumption of rodents can be calculated. The results are presented in Table below.

**Table 2-21 Expected concentrations of brodifacoum in non-target animals (predators/carnivores) due to secondary poisoning after a single day of exposure (concentration of brodifacoum in rodenticide bait 0.005%). Rodents fed 100% on rodenticide and predators/carnivores fed 50% on poisoned rodents**

Species	Body weight (g)	Daily mean food intake (g.d <sup>-1</sup> )	Normal susceptible rodents caught on day 5		Resistant rodents caught on day 14	
			Amount a.i. (mg) <sup>1</sup>	Conc. (mg.kg <sup>-1</sup> ) <sup>2</sup>	Amount a.i. (mg) <sup>1</sup>	Conc. (mg.kg <sup>-1</sup> ) <sup>2</sup>
Barn owl ( <i>Tyto alba</i> )	294	72.9	0.25	0.86	0.30	1.03
Kestrel ( <i>Falco tinnunculus</i> )	209	78.7	0.27	1.31	0.33	1.56
Little owl ( <i>Athene noctua</i> )	164	46.4	0.16	0.98	0.19	1.17
Tawny owl ( <i>Strix aluco</i> )	426	97.1	0.34	0.79	0.40	0.94
Fox ( <i>Vulpes vulpes</i> )	5700	520.2	1.80	0.32	2.15	0.38
Polecat ( <i>Mustela putorius</i> )	689	130.9	0.45	0.66	0.54	0.79
Stoat ( <i>Mustela erminea</i> )	205	55.7	0.19	0.94	0.23	1.12
Weasel ( <i>Mustela nivalis</i> )	63	24.7	0.09	1.36	0.10	1.62

<sup>1</sup> Amount a.i. consumed by non-target animal  
<sup>2</sup> Conc. in non-target animal

## 2.8.5 Risk characterisation for the environment

### 2.8.5.1 Primary poisoning

Risk characterization for the environment is done quantitatively by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC and/or LD<sub>50</sub>) according to the guidance in Technical guidance document (TGD, 2003) and “Emission Scenario document for biocides used as rodenticides” (Larsen, 2003, ESD PT14).

The environmental risk characterization has been carried out for brodifacoum.

#### 2.8.5.1.1 Tier 1 assessment

The PEC value for Tier 1 assessment is compared to the long-term PNEC for mammals and birds.

**Table 22: Tier 1 risk characterization of primary poisoning – Long-Term**



	<b>PEC<sup>1</sup> mg.kg food<sup>-1</sup></b>	<b>PNEC<sup>1</sup> mg.kg food<sup>-1</sup></b>	<b>PEC/PNEC</b>
<b>Birds</b>	25	1.3E-04	192 308
<b>Mammals</b>	25	2.22E-04	112 613

<sup>1</sup> Concentration of brodifacoum in food.

For mammals and birds, the resulting PEC/PNEC ratios reveal high risks of long-term primary poisoning.

**Tier 2 assessment – acute**

For the acute situation of primary poisoning, only a qualitative risk assessment is carried out in accordance with the decision from TM III-06. In this Tier 2 acute qualitative assessment, the PEC values are compared to the LD<sub>50</sub> values.

**Table 23: Tier 2 acute qualitative risk assessment of primary poisoning**

	<b>PEC<sub>oral</sub><sup>1</sup> mg.kg<sup>-1</sup> bw</b>		<b>LD<sub>50</sub> dose mg.kg<sup>-1</sup> bw d<sup>-1</sup></b>	<b>PEC<sub>oral</sub> &gt; LD<sub>50</sub> (y/n)</b>	
	<b>Step 1</b>	<b>Step 2</b>		<b>Step 1</b>	<b>Step 2</b>
<b>Dog</b>	1.14	0.82	0.40	y	y
<b>Pig</b>	0.19	0.14		n	n
<b>Pig young</b>	0.60	0.43		y	y
<b>Tree sparrow</b>	8.64	6.22	0.31	y	y
<b>Chaffinch</b>	7.50	5.40		y	y
<b>Wood pigeon</b>	2.71	1.95		y	y
<b>Pheasant</b>	2.70	1.94		y	y

<sup>1</sup> PEC<sub>oral</sub> = ETE, concentration of brodifacoum after one meal

This comparison indicates that the situation for mammals is uncertain. Dogs and young pigs are at risk while pigs are not at risk but very close to the trigger value. On the other hand, this comparison indicates that all birds are at risk for acute primary poisoning.

**Tier 2 assessment – long-term**

The PEC values are compared to the PNEC values.

**Table 24: Tier 2 long-term risk assessment of primary poisoning**

	PEC <sub>oral</sub> <sup>1</sup> mg.kg <sup>-1</sup> <sub>bw</sub>	PNEC mg.kg <sup>-1</sup> <sub>bw</sub> d <sup>-1</sup>	PEC /PNEC
	Step 2		
<b>Dog</b>	0.57	1.1E-05	<b>51 818</b>
<b>Pig</b>	0.09		<b>8 182</b>
<b>Pig young</b>	0.30		<b>27 273</b>
<b>Tree sparrow</b>	4.35	1.3E-05	<b>334 615</b>
<b>Chaffinch</b>	3.78		<b>290 769</b>
<b>Wood pigeon</b>	1.37		<b>105 385</b>
<b>Pheasant</b>	1.36		<b>104 615</b>

<sup>1</sup> PEC<sub>oral</sub> = EC, concentration of brodifacoum after one day of elimination

The risk characterization indicates a very high risk to non-target mammals and birds from direct eating of bait. Primary poisoning incidents can be minimized by preventing the access of non-target animals to the baits. It is assumed in the ESD that if the rodenticide baits are use according to the label instructions, the risk for primary poisoning is negligible. However, it is stated at the EU level that it may not be possible to exclude exposure of all non-target animals, as the baits have to be accessible to target rodents, they may as well be accessible to non-target mammals birds of equal or smaller size than the target rodents.

Nevertheless, as the product FANGA RAT-DICAL TECH is intended to be used indoor and in bait stations only, primary poisoning can therefore be considered negligible as domestic animals can be kept away from the product, and wild animals other than rats and mice are not expected to be found inside buildings.

### 2.8.5.2 Secondary poisoning

The only relevant scenario of secondary poisoning in the case of an indoor application only is for the rodent-eating mammal or bird.

#### 2.8.5.2.1 Tier 1 assessment, acute

The PEC<sub>oral</sub> are compared to the LC<sub>50</sub> value presented in the section above for qualitative risk assessment in accordance with the decisions taken at the TMII-06.

**Table 25: Tier 1 long-term risk assessment of secondary poisoning**

Non-target animal	PEC <sub>oral</sub> mg.kg <sup>-1</sup> <sub>bw</sub>			LC <sub>50</sub> dose mg.kg <sup>-1</sup> <sub>food</sub>	PEC <sub>oral</sub> > LC <sub>50</sub> (y/n)		
	PD=0.2	PD=0.5	PD=1		PD=0.2	PD=0.5	PD=1
<b>Birds</b>	1.4	3.5	7	8	n	n	n
<b>Mammals</b>	1.4	3.5	7	0.72	y	y	y

PEC<sub>oral</sub> = Expected concentration in rodent caught on day 5 after meal

PD = fraction of the food type in the diet

This qualitative risk assessment doesn't indicate risk for birds at all fractions of the food type in the diet and with a PEC in rodent caught on day 5 after meal, and indicates risk for mammals at all fractions of food type in the diet and with a PEC in rodent caught on day 5 after meal.

### Tier 1 assessment, long-term

To assess the risk of long-term secondary poisoning, the PEC in rodents after 5 days is used and compared to the long-term PNEC<sub>oral</sub> for birds and mammals.

**Table 26: Tier 1 long-term risk assessment of secondary poisoning**

Non-target animal	PEC <sub>oral</sub> mg.kg <sup>-1</sup> bw	PNEC mg.kg <sup>-1</sup> food	PEC /PNEC
<b>Birds</b>	7	1.3E-04	53 846
<b>Mammals</b>	7	2.22E-04	31 532

PEC<sub>oral</sub> = Expected concentration in rodent caught on day 5 after meal

The tier 1 long-term assessment indicates very high risks of long-term secondary poisoning for birds and mammals.

**Tier 2 assessment, long-term**

**Table 27: Tier 2 long-term risk assessment of secondary poisoning**

Species	PEC (mg/kg bw)		PNEC (mg/kg bw)	PEC/PNEC	
	day 5	day 14		day 5	day 14
<b>Barn owl (<i>Tyto alba</i>)</b>	0.85	1.05	1.3E-05	<b>65 385</b>	<b>80 769</b>
<b>Kestrel (<i>Falco tinnunculus</i>)</b>	1.3	1.55		<b>100 000</b>	<b>119 231</b>
<b>Little owl (<i>Athene noctua</i>)</b>	1.0	1.15		<b>76 923</b>	<b>88 462</b>
<b>Tawny owl (<i>Strix aluco</i>)</b>	0.8	0.95		<b>61 538</b>	<b>73 077</b>
<b>Fox (<i>Vulpes vulpes</i>)</b>	0.3	0.4	1.1E-05	<b>27 273</b>	<b>36 364</b>
<b>Polecat (<i>Mustela putorius</i>)</b>	0.65	0.8		<b>59 091</b>	<b>72 727</b>
<b>Stoat (<i>Mustela erminea</i>)</b>	0.95	1.15		<b>86 364</b>	<b>104 545</b>
<b>Weasel (<i>Mustela nivalis</i>)</b>	1.35	1.65		<b>122 727</b>	<b>150 000</b>

The tier 2 risk characterisation shows very high risks for secondary poisoning at long-term for birds and mammals.

However, considering the fact that FANGA RAT-DICAL TECH is intended to be used indoor only, it can be assumed that, applying use restrictions (such as collecting dead rodents), the risk for secondary poisoning will be lower.

Nevertheless, in order to reduce the risk of secondary poisoning, it is very important to follow the use instructions of the rodenticide baits. The risk reduction measures are considered in the following section.

➤ Renewal application - 2017

Table 2-28 PEC groundwater due to use of FANGA RAT DICAL TECH in and around building

Baiting scenario (ESD PT14)	PEC groundwater ( $\mu\text{g}_{\text{brodifacoum}}\cdot\text{L}^{-1}$ )	Threshold value in groundwater ( $\mu\text{g}\cdot\text{L}^{-1}$ )	Risk characterization
<b>Realistic worst case</b>			
Rat treatment	1.49E-02	0.03*	Acceptable
Mice treatment	1.49E-02		
<b>Typical scenario</b>			
Rat treatment	4.47E-03	0.03*	Acceptable
Mice treatment	4.47E-03		

\*0.03 $\mu\text{g}/\text{L}$  corresponds on the threshold value for the toxicity in drinking water.

Baiting scenario (EUBEES 2)	PEC <sub>soil</sub> (mg /kg wwt)	PNEC <sub>soil</sub> (mg /kg wwt)	PEC/PNEC
Typical use (rat treatment)	1.73E-01	0.88	0.197
Typical use (mice treatment)	3.46E-02		0.039

\*0.03 $\mu\text{g}/\text{L}$  corresponds on the threshold value for the toxicity in drinking water.

Due to the new threshold value in groundwater, the risk is unacceptable. A FOCUS modelling was realised to refine the PEC groundwater: Application rate is calculated from Brodifacoum concentration in soil of 3.825g/application as a worst case leading to a dose rate of 76.5kg.ha<sup>-1</sup>.

Model used	FOCUS PEARL 4.4.4.
Years of simulation	1
Application rate	0.003825 kg.ha <sup>-1</sup>
Standard crop for arable land	Alfalfa
Application depth	Incorporation 0 cm
Date of application	Twelve applications per year
Molar mass	523.4 g.mol <sup>-1</sup>
Vapour pressure	1E-06 Pa at 20°C
Water solubility	0.240 mg.L <sup>-1</sup> at 20°C
Kom	5310.3 L.kg <sup>-1</sup> at 25°C
Freundlich exponent	1

DT <sub>50</sub> soil	298 d at 12°C
Coefficient for uptake for plant	0
Molar activation energy	54 kJ.mol <sup>-1</sup>

**RESULTS :**

RESULT_TEXT	BRODIFACOUM	LOCATION	IRRIGATION_SCHEME
Concentration closest to the 80th percentile (ug/L)	0.000000	CHATEAUDUN	FOCUS
Concentration closest to the 80th percentile (ug/L)	0.000000	HAMBURG	No
Concentration closest to the 80th percentile (ug/L)	0.000000	JOKIOINEN	No
Concentration closest to the 80th percentile (ug/L)	0.000000	KREMSMUNSTER	No
Concentration closest to the 80th percentile (ug/L)	0.000000	OKEHAMPTON	No
Concentration closest to the 80th percentile (ug/L)	0.000000	PIACENZA	FOCUS
Concentration closest to the 80th percentile (ug/L)	0.000000	PORTO	FOCUS
Concentration closest to the 80th percentile (ug/L)	0.000000	SEVILLA	FOCUS
Concentration closest to the 80th percentile (ug/L)	0.000000	THIVA	FOCUS

According to the FOCUS modelling, the risk is acceptable in groundwater for the use of FANGA RAT DICAL TECH in waste dump.

No new ecotoxicological information has been submitted at the renewal of the approval of the active substance brodifacoum and in the product dossier. Therefore, the environmental risk assessment conclusions regarding the reference product and the major changes remain unchanged.

**2.8.5.3 Conclusion of the risk assessment for the environment**

No studies were conducted with the product FANGA RAT-DICAL TECH for the environment part; therefore the environmental risk assessment has been carried out with data from the Combined AR of brodifacoum. The environmental risk is considered as limited for the indoor use by professionals, in strict compliance with the specific use instructions of rodenticidal baits and the use restrictions to reduce the risk for primary and secondary poisoning.

**Disposal considerations**

- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment **Erreur ! Signet non défini..**
- Dispose of the tamper-resistant bait boxes and covered bait stations, packaging, uneaten baits and dead rodents in accordance with local requirements.
- Never wash the tamper-resistant bait boxes and covered bait stations with water.
- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.

- Remove all bait points after the end of treatment.

***Required information linked to risk assessment for environment***

None.

**Conclusion of the renewal 2017**

No studies were conducted with the product FANGA RAT DICAL TECH for the environment part; therefore the environmental risk assessment has been carried out with data from the combined CAR of brodifacoum. The environmental risk is considered as acceptable for the intended uses except for the primary and secondary poisoning. The specific use restriction must be applied to reduce the risk for primary and secondary poisoning.

Risk mitigation measures have been proposed in the brodifacoum approval regulation

**2.9 Measures to protect man, animals and the environment**

*See Summary of Product Characteristics (SPC).*

### 3 Proposal for decision - Minor change 2022

#### 1 . Administrative information

##### 1.1 Trade name(s) of the product

Trade name(s)	
	FANGA 5 CEREALES 25 FANGA ABSOLU MIX 25 FESTIN DU RONGEUR MIX 25 ABSOLUTE WAY MIX 25 E'RAT-SE MIX 25 STOP RAT MIX BROD 25 CÉRÉALE SUPER CÉRÉALE EXTRA EXCELL'CEREALE SUPP'BD CÉRÉALE STOP BD CÉRÉALE RONGEURS BD CÉRÉALE RODENT BD CEREAL

##### 1.2 Authorisation holder

Name and address of the authorisation holder	Name	TRIPLAN S.A.
	Address	BP258 La Poste Française AD500 Andorra La Vella ANDORRA
Authorisation number	FR-2019-0048	
<i>R4BP asset reference number</i>	FR-0020621-0000	
Date of the authorisation	24/08/2022	
Expiry date of the authorisation	01/07/2024	

##### 1.3 Manufacturer(s) of the product

Name of manufacturer	SOFAR FRANCE
Address of manufacturer	SOFAR FRANCE ZA DU DREVERS BP 02 29190 Pleyben FRANCE
Location of manufacturing sites	SOFAR FRANCE ZA DU DREVERS BP 02 29190 Pleyben FRANCE

Name of manufacturer	HDA
Address of manufacturer	HDA ZA LA CHARME MENETROL 63200 Riom FRANCE
Location of manufacturing sites	HDA ZA LA CHARME MENETROL 63200 Riom FRANCE

Name of manufacturer	RATOUCY SAS
Address of manufacturer	RATOUCY SAS

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	29 rue de la Forêt LOOZE - BP 145 89303 Joigny Cedex FRANCE
<b>Location of manufacturing sites</b>	RATOUCY SAS 29 rue de la Forêt 89300 LOOZE FRANCE

<b>Name of manufacturer</b>	AEDES PROTECTA
<b>Address of manufacturer</b>	75 rue d'Orgemont 95210 SAINT-GRATIEN FRANCE
<b>Location of manufacturing sites</b>	LIEU DIT DOUILLAC 81310 PARISOT FRANCE

<b>Name of manufacturer</b>	IRIS
<b>Address of manufacturer</b>	IRIS 1126A Avenue du Moulinas – Route de Saint-Privat 30340 Salindres FRANCE
<b>Location of manufacturing sites</b>	IRIS 1126A Avenue du Moulinas – Route de Saint-Privat 30340 Salindres FRANCE

<b>Name of manufacturer</b>	FARMAVIT OOD
<b>Address of manufacturer</b>	Bul Tsar Boris III N°63, Office n°1 1612 Sofia BULGARIA
<b>Location of manufacturing sites</b>	Industrialna 2 str Pleven District 5960 Guliantzi BULGARIA

<b>Name of manufacturer</b>	NOXIMA
<b>Address of manufacturer</b>	Carrefour Jean Monnet – Lacroix Saint-Ouen 60201 Compiègne FRANCE
<b>Location of manufacturing sites</b>	Carrefour Jean Monnet – Lacroix Saint-Ouen 60201 Compiègne FRANCE

<b>Name of manufacturer</b>	INDUPHARMA S.r.l.
<b>Address of manufacturer</b>	Via Sorgaglia 40 I-35020 Arre (PD) ITALIA
<b>Location of manufacturing sites</b>	Via Sorgaglia 40 I-35020 Arre (PD) ITALIA

<b>Name of manufacturer</b>	FARMA-CHEM SA
<b>Address of manufacturer</b>	Industrial Area of Sindos P.O.BOX 1026 Block 53 Zone C 57022 Thessaloniki GREECE



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<b>Location of manufacturing sites</b>	Industrial Area of Sindos P.O.BOX 1026 Block 53 Zone C 57022 Thessaloniki GREECE
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<b>Name of manufacturer</b>	AGGRESS
<b>Address of manufacturer</b>	EL. VENIZELOU 158 A, 16341 ATHENS Greece
<b>Location of manufacturing sites</b>	ARMA THEBES, 32200 VOIOTIA Greece

<b>Name of manufacturer</b>	AGROLOGY SA
<b>Address of manufacturer</b>	P.O.BOX 1089 Industrial Area of Thessaloniki 57022 Thessaloniki GREECE
<b>Location of manufacturing sites</b>	P.O.BOX 1089 Industrial Area of Thessaloniki 57022 Thessaloniki GREECE

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

<b>Active substance</b>	Brodifacoum
<b>Name of manufacturer</b>	ACTIVA S.R.L.
<b>Address of manufacturer</b>	Via Feltre 32 20132 Milan ITALIA
<b>Location of manufacturing sites</b>	Dr. TEZZA S.R.L. Via Tre Ponti 22 37050 S. Maria di Zevio (VR) ITALIA

## 2 Product composition and formulation


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

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

### 2.2 Type of formulation

Ready-to-use bait: grain
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### 3 Hazard and precautionary statements

Classification	
Hazard category	STOT RE 2
Hazard statement	H373
Labelling	
Signal words	 Warning
Hazard statements	H373 (blood): May cause damage to organs through prolonged or repeated exposure
Precautionary statements	P101: If medical advice is needed, have product container or label at hand*. P102: Keep out of reach of children*. P103: Read label before use*. P260: Do not breathe dust/fumes/gas/mist/vapours/spray. P314: Get medical advice/attention if you feel unwell. P501: Dispose of contents/container in accordance to... [ <i>... in accordance with local/regional/national/international regulation</i> ]
Note	*required as the product is for non-professional use

### 4 Authorised use(s)

#### 4.1 Use description

Table 29. 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)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (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 <sup>14</sup> - [ <i>Covered and protected baiting points</i> ]
Application rate(s) and frequency	Bait products: - rats: 100 g / bait point separated by 5-10 meters - mice: 40 g of product / bait station at separated to 1-2 meters
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)  FANGA RAT-DICAL TECH is supplied in: - Rats : 10, 20, 25, 50, 100 g PE/PP sachets

<sup>14</sup> See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations.

	<ul style="list-style-type: none"> <li>- Mice : 10, 20, 40 g PE/PP sachets</li> </ul> <p>Sachets are packed in:</p> <ul style="list-style-type: none"> <li>- Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg)</li> <li>- PE/PP bucket (5-10-15-20-25 kg)</li> <li>- PE/PP bags (5-10-15-20-25 kg)</li> <li>- Carton box (5-10-12-15-20-50 kg)</li> <li>- Metal box without lacquer (5-10-15-20-25 kg)</li> <li>- Prefilled tamper resistant PET/PP/PE/PVC bait station</li> </ul> <p>FANGA RAT-DICAL TECH is also supplies in loose:</p> <ul style="list-style-type: none"> <li>- Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg)</li> <li>- PE/PP buckets (5-10-15-20-25 kg)</li> <li>- PE/PP bags (5-10-15-20-25 kg)</li> <li>- Carton box (5-10-12-15-20-50 kg)</li> <li>- Metal box without lacquer (5-10-15-20-25 kg)</li> <li>- Prefilled secured tamper resistant PET/PP/PE/PVC bait station</li> </ul>
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**4.1.1 Use-specific instructions for use**

<ul style="list-style-type: none"> <li>- Remove the remaining product at the end of treatment period.</li> <li>- <i>[When available]</i> Follow any additional instructions provided by the relevant code of best practice.</li> </ul>
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**4.1.2 Use-specific risk mitigation measures**

<ul style="list-style-type: none"> <li>- 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 <i>[in accordance with the applicable code of good practice, if any]</i>.</li> <li>- 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.</li> <li>- 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.</li> <li>- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.</li> <li>- Do not use the product in pulsed baiting treatments.</li> </ul>
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**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**

<ul style="list-style-type: none"> <li>- When placing bait points close to water drainage systems, ensure that bait contact with water is avoided.</li> </ul>
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**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**

<b>Product Type</b>	14
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism(s) (including development stage)</b>	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)
<b>Field(s) of use</b>	Outdoor around buildings
<b>Application method(s)</b>	Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - <i>[Covered and protected baiting points]</i>
<b>Application rate(s) and frequency</b>	Bait products: - rats: 100 g / bait point separated by 5-10 meters - mice: 40 g of product / bait station at separated to 1-2 meters
<b>Category(ies) of users</b>	Trained professionals
<b>Pack sizes and packaging material</b>	Minimum pack size of 3 kg. <b>(In France only:</b> minimum pack size of 5 kg)  FANGA RAT-DICAL TECH is supplied in: - Rats : 10, 20, 25, 50, 100 g PE/PP sachets - Mice : 10, 20, 40 g PE/PP sachets  Sachets are packed in: - Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg) - PE/PP bucket (5-10-15-20-25 kg) - PE/PP bags (5-10-15-20-25 kg) - Carton box (5-10-12-15-20-50 kg) - Metal box without lacquer (5-10-15-20-25 kg) - Prefilled tamper resistant PET/PP/PE/PVC bait station  FANGA RAT-DICAL TECH is also supplies in loose: - Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg) - PE/PP buckets (5-10-15-20-25 kg) - PE/PP bags (5-10-15-20-25 kg) - Carton box (5-10-12-15-20-50 kg) - Metal box without lacquer (5-10-15-20-25 kg) - Prefilled secured tamper resistant PET/PP/PE/PVC bait station

#### **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**

**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 4.3. Use description**

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

<b>Product Type</b>	14
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism(s) (including development stage)</b>	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat) <i>Mus musculus</i> (mice)
<b>Field(s) of use</b>	Outdoor open areas <input type="checkbox"/> Outdoor waste dumps <input type="checkbox"/>
<b>Application method(s)</b>	- Ready-to-use bait to be used in tamper-resistant bait stations. - [Covered and protected baiting points]
<b>Application rate(s) and frequency</b>	Bait products: - rats: 100 g / bait point separated by 5-10 meters - mice: 40 g of product / bait station at separated to 1-2 meters
<b>Category(ies) of users</b>	Trained professionals only
<b>Pack sizes and packaging material</b>	Minimum pack size of 3 kg. (In France only: minimum pack size of 5 kg)  FANGA RAT-DICAL TECH is supplied in: - Rats : 10, 20, 25, 50, 100 g PE/PP sachets - Mice : 10, 20, 40 g PE/PP sachets  Sachets are packed in: - Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg) - PE/PP bucket (5-10-15-20-25 kg) - PE/PP bags (5-10-15-20-25 kg) - Carton box (5-10-12-15-20-50 kg) - Metal box without lacquer (5-10-15-20-25 kg) - Prefilled tamper resistant PET/PP/PE/PVC bait station

	<p>FANGA RAT-DICAL TECH is also supplies in loose:</p> <ul style="list-style-type: none"> <li>- Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg)</li> <li>- PE/PP buckets (5-10-15-20-25 kg)</li> <li>- PE/PP bags (5-10-15-20-25 kg)</li> <li>- Carton box (5-10-12-15-20-50 kg)</li> <li>- Metal box without lacquer (5-10-15-20-25 kg)</li> <li>- Prefilled secured tamper resistant PET/PP/PE/PVC bait station</li> </ul>
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**4.3.1 Use-specific instructions for use**

<ul style="list-style-type: none"> <li>- Protect bait from the atmospheric conditions. Place the bait stations in areas not liable to flooding.</li> <li>- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.</li> <li>- Remove the remaining product at the end of treatment period.</li> <li>- <i>[When available]</i> Follow any additional instructions provided by the relevant code of best practice.</li> <li>- <i>[For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species].</i></li> </ul>
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**4.3.2 Use-specific risk mitigation measures**

<ul style="list-style-type: none"> <li>- 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 <i>[in accordance with the applicable code of good practice, if any]</i>.</li> <li>- 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.</li> <li>- Do not apply this product directly in the burrows.</li> </ul>
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**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**

<ul style="list-style-type: none"> <li>- 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.</li> </ul>
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**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**

<b>Product Type</b>	14
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism(s) (including development stage)</b>	<i>Mus musculus</i> (house mice)
<b>Field(s) of use</b>	Indoor

<b>Application method(s)</b>	Ready-to-use bait to be used in tamper-resistant bait stations <sup>15</sup>
<b>Application rate(s) and frequency</b>	- mice: 40 g of product / bait station at separated to 1-2 meters
<b>Category(ies) of users</b>	Professionals
<b>Pack sizes and packaging material</b>	<p>Minimum pack size of 3 kg.  <b>(In France only:</b> minimum pack size of 5 kg)</p> <p>FANGA RAT-DICAL TECH is supplied in:</p> <ul style="list-style-type: none"> <li>- Mice : 10, 20, 40 g PE/PP sachets</li> </ul> <p>Sachets are packed in:</p> <ul style="list-style-type: none"> <li>- Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg)</li> <li>- PE/PP bucket (5-10-15-20-25 kg)</li> <li>- PE/PP bags (5-10-15-20-25 kg)</li> <li>- Carton box (5-10-12-15-20-50 kg)</li> <li>- Metal box without lacquer (5-10-15-20-25 kg)</li> <li>- Prefilled tamper resistant PET/PP/PE/PVC bait station</li> </ul> <p>FANGA RAT-DICAL TECH is also supplies in loose:</p> <ul style="list-style-type: none"> <li>- Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg)</li> <li>- PE/PP buckets (5-10-15-20-25 kg)</li> <li>- PE/PP bags (5-10-15-20-25 kg)</li> <li>- Carton box (5-10-12-15-20-50 kg)</li> <li>- Metal box without lacquer (5-10-15-20-25 kg)</li> <li>- Prefilled secured tamper resistant PET/PP/PE/PVC bait station</li> </ul>

**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**

<sup>15</sup> See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations.

**4.5 Use description**

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

<b>Product Type</b>	14
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism(s) (including development stage)</b>	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)
<b>Field(s) of use</b>	Indoor
<b>Application method(s)</b>	Ready-to-use bait to be used in tamper-resistant bait stations
<b>Application rate(s) and frequency</b>	Bait products: - rats: 100 g / bait point separated by 5-10 meters
<b>Category(ies) of users</b>	Professionals
<b>Pack sizes and packaging material</b>	Minimum pack size of 3 kg. <b>(In France only:</b> minimum pack size of 5 kg)  FANGA RAT-DICAL TECH is supplied in: - Rats : 10, 20, 25, 50, 100 g PE/PP sachets  Sachets are packed in: - Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg) - PE/PP bucket (5-10-15-20-25 kg) - PE/PP bags (5-10-15-20-25 kg) - Carton box (5-10-12-15-20-50 kg) - Metal box without lacquer (5-10-15-20-25 kg) - Prefilled tamper resistant PET/PP/PE/PVC bait station  FANGA RAT-DICAL TECH is also supplies in loose: - Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg) - PE/PP buckets (5-10-15-20-25 kg) - PE/PP bags (5-10-15-20-25 kg) - Carton box (5-10-12-15-20-50 kg) - Metal box without lacquer (5-10-15-20-25 kg) - Prefilled secured tamper resistant PET/PP/PE/PVC bait station

**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**

**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**

- 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**

<b>Product Type</b>	14
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism(s) (including development stage)</b>	Mus musculus (house mice) Rattus norvegicus (brown rat) Rattus rattus (black or roof rat)
<b>Field(s) of use</b>	Outdoor around buildings
<b>Application method(s)</b>	Ready-to-use bait to be used in tamper-resistant bait stations
<b>Application rate(s) and frequency</b>	Bait products: - rats: 100 g / bait point separated by 5-10 meters - mice: 40 g / bait point separated by 1-2 meters
<b>Category(ies) of users</b>	Professionals
<b>Pack sizes and packaging material</b>	<p>Minimum pack size of 3 kg. <b>(In France only:</b> minimum pack size of 5 kg)</p> <p>FANGA RAT-DICAL TECH is supplied in:</p> <ul style="list-style-type: none"> <li>- Rats : 10, 20, 25, 50, 100 g PE/PP sachets</li> <li>- Mice : 10, 20, 40 g PE/PP sachets</li> </ul> <p>Sachets are packed in:</p> <ul style="list-style-type: none"> <li>- Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg)</li> <li>- PE/PP bucket (5-10-15-20-25 kg)</li> <li>- PE/PP bags (5-10-15-20-25 kg)</li> <li>- Carton box (5-10-12-15-20-50 kg)</li> <li>- Metal box without lacquer (5-10-15-20-25 kg)</li> <li>- Prefilled tamper resistant PET/PP/PE/PVC bait station</li> </ul> <p>FANGA RAT-DICAL TECH is also supplies in loose:</p> <ul style="list-style-type: none"> <li>- Paper bags, several layers with one or without plastic film in PE/PP (5-10-15-20-25 kg)</li> <li>- PE/PP buckets (5-10-15-20-25 kg)</li> <li>- PE/PP bags (5-10-15-20-25 kg)</li> <li>- Carton box (5-10-12-15-20-50 kg)</li> <li>- Metal box without lacquer (5-10-15-20-25 kg)</li> <li>- Prefilled secured tamper resistant PET/PP/PE/PVC bait station</li> </ul>

**4.6.1 Use-specific instructions for use**

<p>- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.</p>
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- 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**

- 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**

- 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**

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

**4.7 Use description**

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

<b>Product Type</b>	14
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism(s) (including development stage)</b>	<i>Mus musculus</i> (house mice)
<b>Field(s) of use</b>	Indoor
<b>Application method(s)</b>	Ready-to-use bait [ <i>in sachets for loose bait</i> ] to be used in tamper-resistant bait stations <sup>16</sup> .
<b>Application rate(s) and frequency</b>	Bait products: - mice: 40 g / bait point separated by 1-2 meters
<b>Category(ies) of users</b>	General public
<b>Pack sizes and packaging material</b>	Maximum pack size of 150 g.  FANGA RAT-DICAL TECH is supplied in: - Mice : 10, 20, 40 g PE/PP sachets  Sachets are packed in: - PE/PP bucket (up to 150 g) - Carton box (up to 150 g) - PE/PP film (up to 150 g) - Metal box without lacquer (up to 150 g) - PE/PP containers (up to 150 g)

<sup>16</sup> See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations.

	- Prefilled secured tamper resistant PET/PP/PE/PVC bait box
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**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.
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**4.7.2 4.1.2 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 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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**4.8 Use description**

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

<b>Product Type</b>	14
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism(s) (including development stage)</b>	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)
<b>Field(s) of use</b>	Indoor.
<b>Application method(s)</b>	Ready-to-use bait [ <i>in sachets for loose bait</i> ] to be used in tamper-resistant bait stations <sup>2</sup> .
<b>Application rate(s) and frequency</b>	Bait products: - rats: 100 g / bait point separated by 5-10 meters
<b>Category(ies) of users</b>	General public
<b>Pack sizes and packaging material</b>	Maximum pack size of 150 g.  FANGA RAT-DICAL TECH is supplied in: - Rats : 10, 20, 25, 50, 100 g PE/PP sachets  Sachets are packed in: - PE/PP bucket (up to 150 g) - Carton box (up to 150 g) - PE/PP film (up to 150 g) - Metal box without lacquer (up to 150 g) - PE/PP containers (up to 150 g) - Prefilled secured tamper resistant PET/PP/PE/PVC bait box

**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
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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**

**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**

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

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

**4.9 Use description**

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

<b>Product Type</b>	14
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism(s) (including development stage)</b>	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)
<b>Field(s) of use</b>	Outdoor around buildings
<b>Application method(s)</b>	Ready-to-use bait [ <i>in sachets for loose bait</i> ] to be used in tamper-resistant bait stations <sup>2</sup> .
<b>Application rate(s) and frequency</b>	Bait products: - rats: 100 g / bait point separated by 5-10 meters
<b>Category(ies) of users</b>	General public
<b>Pack sizes and packaging material</b>	Maximum pack size of 150 g.  FANGA RAT-DICAL TECH is supplied in: - Rats : 10, 20, 25, 50, 100 g PE/PP sachets  Sachets are packed in: - PE/PP bucket (up to 150 g) - Carton box (up to 150 g) - PE/PP film (up to 150 g) - Metal box without lacquer (up to 150 g) - PE/PP containers (up to 150 g) - Prefilled secured tamper resistant PET/PP/PE/PVC bait box

**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

- Do not apply this product directly in the burrows.

#### 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

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

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

## 5 General directions for use

### 5.1 Instructions for use

#### **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.
- 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 PROFESSIONALS 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 PROFESSIONALS ONLY** Remove the remaining bait or the bait stations at the end of the treatment period.

- *Instructions for use that are "bait-specific":*

- *Do not open the sachets containing the bait.*

### **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**

### **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

- 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

- 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

- 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 years

### 6 Other information

- **(in France only** : The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance brodifacoum. 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.



## 4 Appendices

**Annex 1: Summary of product characteristics**

*See separated file.*

Annex 2: List of studies reviewed

4.1.1.1.1 List of new data<sup>17</sup> submitted in support of the evaluation of the active substance

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

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
B3	B3.1, B3.5, B3.7, B3.8	Forand V	2012	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54±2°C on FANGA RAT-DICAL TECH in compliance with CIPAC MT 46.3 (CIPAC Handbook J – 2000). DEFITRACES, report n°11-920010-029 of 15 February 2012, GLP, unpublished.	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B3	B3.2/3, B3.4, B3.6, B3.8	Colombies N	2012	Physico chemical tests on FANGA RAT-DICAL TECH. DEFITRACES, report n° 11-920010-028 of 22 February 2012, GLP, unpublished.	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

<sup>17</sup> Data which have not been already submitted for the purpose of the Annex I inclusion.

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
B3	B3.7, B3.8, B3.12	Grevin P	2012	Physico chemical tests before and after an accelerated storage procedure for 14 days at 54 ± 2°C on FANGA RAT-DICAL TECH. DEFITRACES, Report 12-920010-011 of 27 September 2012, GLP, unpublished	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B4	B4.1.1	Ricau H	2012	Analytical method validation for the determination of brodifacoum in the FANGA BLOC SP PRO in compliance with SANCO/3030/99 rev.4 from 11/07/00. DEFITRACES, Report n° 11-920010-015 of 23 January 2012, GLP, unpublished.	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B4	B4.1.1	Ricau H	2012	Analytical method validation for the determination of brodifacoum in the FANGA BLOC SP PRO in compliance with SANCO/3030/99 rev.4 from 11/07/00. DEFITRACES, amended report n° 11-920010-015 of 04 May 2012, GLP, unpublished.	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
B4	B4.1.2	Ricau H	2012	Analytical method validation for the determination of brodifacoum in the FANGA RAT-DICAL TECH in compliance with SANCO/3030/99 rev.4 from 11/07/00. DEFITRACES, Report n° 11-920010-031 of 28 February 2012, GLP, unpublished.	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B5	B5.10.2	██████████	2012	Palatability of « FANGA RAT-DICAL TECH » (25 ppm brodifacoum) ready-to-use bait targeting brown rat ( <i>Rattus norvegicus</i> ) and house mouse ( <i>Mus musculus</i> ). Walloon Agricultural Research Centre – Department Pesticide Research, Report n° ROD 2012 06 of 24 May 2012, not GLP, unpublished.	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B5	B5.10.2/01	██████████	2013	Study on the palatability and the efficacy of a maize bait containing 0.0025% brodifacoum in brown rat ( <i>Rattus norvegicus</i> ). Biolytics, Study n° 12-TOX024-13 of 24 January 2013, not GLP (unpublished).	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
B5	B5.10.2/02	[REDACTED]	2013	Study on the palatability and efficacy of a 0.0025% brodifacoum corn bait in house mouse ( <i>Mus musculus</i> ). Biolytics, Study n° 12-TOX024-9 of 24 January 2013, not GLP (unpublished).	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B5	B5.10.2/03	[REDACTED]	2013	Evaluation of the efficacy of a maize rodenticide (FANGA RAT-DICAL TECH) containing 0.0025% brodifacoum for the control of mouse infestation. One trial, 1 site: Rhone, France, 2012-2013. Biolytics, Final Report, Study n° 12-TOX024-16 of 24 January 2013, not GLP (unpublished).	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B5	B5.10.2	[REDACTED]	2014	Efficacy evaluation of FANGA RAT DICAL TECH (brodifacoum 0,0025% w/w a.i., crush corn bait) against Roof rat ( <i>Rattus rattus</i> L.) in Italy	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B5	B5.10.2	[REDACTED]	2015	study on the palatability and efficacy of a 0.0025% w/w brodifacoum maize bait in brown rat ( <i>Rattus norvegicus</i> )	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B5	B5.10.2	[REDACTED]	2015	Study on the palatability and efficacy of a 0.0025% w/w brodifacoum maize bait in black rat ( <i>Rattus rattus</i> )	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
B5	B5.10.2	[REDACTED]	2015	Efficacy evaluation of BDM25V1 (brodifacoum 0,0025% w/w a.i., corn bait) against Norway rat ( <i>Rattus norvegicus</i> Berk.) in Italy	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B5	B5.10.2	[REDACTED]	2015	Efficacy evaluation of BDM25V1 (brodifacoum 0,0025% w/w a.i., corn bait) against Roof rat ( <i>Rattus rattus</i> L.) in Italy	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B5	B5.10.2	[REDACTED]	2015	Efficacy evaluation of BDM25V1 (brodifacoum 0,0025% w/w a.i., corn bait) against House mouse ( <i>Mus musculus</i> L.) in Italy	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B6	B6.1.1	[REDACTED]	2012	FANGA BLOC SP PRO evaluation of acute oral toxicity in rats – acute toxic class method. PHYCHER BIO DEVELOPPEMENT, study n°: TAO423-PH-11/0402 of 5 January 2012, GLP (unpublished).	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B6	B6.1.2	[REDACTED]	2012	FANGA BLOC SP PRO evaluation of acute dermal toxicity in rats. PHYCHER BIO DEVELOPPEMENT, study n°: TAD-PH-11/0402 of 5 January 2012, GLP (unpublished).	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
B6	B6.2.1	[REDACTED]	2012	FANGA BLOC SP PRO assessment of acute dermal irritation. PHYCHER BIO DEVELOPPEMENT, study n°: IC-OCDE-PH-11/0402 of 5 January 2012, GLP (unpublished).	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B6	B6.2.2	[REDACTED]	2012	FANGA BLOC SP PRO assessment of acute eye irritation. PHYCHER BIO DEVELOPPEMENT, study n°: IO-OCDE-PH-11/0402 of the 5 January 2012, GLP (unpublished).	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B6	B6.3	[REDACTED]	2012	FANGA BLOC SP PRO assessment of the skin sensitization potential in the mouse using the local lymph node assay (LLNA). PHYCHER BIO DEVELOPPEMENT, study n°: LLNA-PH-11/0402, report n° : LLNA-PH-11/0402-R1 of the 16 January 2012, GLP (unpublished).	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
B6	B6.4	Colas S	2011	FAAR BLE evaluation of skin absorption: in vitro method (non GLP study). Phycher Bio-Développement, Study AC-PH-10/0247a-amended of the 6 June 2011.Non GLP, (unpublished).	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B6	B6.4	Jäger, M	2013	ACTIPELLET-DIFE: In vitro dermal delivery with human skin	TRIPLAN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Add rows as necessary

➤ **Assessment of minor change (2018)**

List of studies for the biocidal product

<b>Author(s)</b>	<b>Year</b>	<b>Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published</b>	<b>Data Protectio n Claimed (Yes/No)</b>	<b>Owner (PUB / ORG)</b>	<b>Date of first submissio n</b>
██████ I	2017	Efficacy evaluation of BDM25V1 (brodifacoum 0,0025% w/w a.i., blue corn bait – aged formulation) against Roof rat (Rattus rattus L.) in Italy SAGEA SR Centro di Saggio s.r.l, 2079.BCD.SAG17	Y	TRIPLAN	27/11/2017
██████	2017	Efficacy evaluation of BDM25V1 (brodifacoum 0,0025% w/w a.i., blue corn bait – aged formulation) against Norway rat (Rattus norvegicus Berk.) in Italy SAGEA SR Centro di Saggio s.r.l, 2078.BCD.SAG17	Y	TRIPLAN	27/11/2017

➤ **Minor change application (FANGA 5 CEREALES 25)- 2022**

List of studies for the biocidal product

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)	Date of first submission
██████████	2020	Efficacy evaluation of BDCE25V1 (brodifacoum 0,0025% w/w a.i., 5 cereals bait - aged formulation) against Norway rat ( <i>Rattus norvegicus</i> Berk.) in Italy	Y	TRIPLAN	11/05/2020
██████████	2020	Efficacy evaluation of BDCE25V1 (brodifacoum 0,0025% w/w a.i., 5 cereals bait - aged formulation) against Roof rat ( <i>Rattus rattus</i> L.) in Italy	Y	TRIPLAN	04/06/2020
██████████ I	2020	Efficacy evaluation of BDCE25V1 (brodifacoum 0,0025% w/w a.i., 5 cereals bait - aged formulation) against House mouse ( <i>Mus musculus</i> L.) in Italy	Y	TRIPLAN	04/06/2020
██████████	2021	Efficacy evaluation of BDCE25V1 (brodifacoum 0,0025% w/w a.i., 5 cereals bait - aged formulation) against Roof rat ( <i>Rattus rattus</i> L.) in Italy	Y	TRIPLAN	03/05/2021
██████████	2020	Palatability/efficacy testing of BDCE25V1 bait according to the "Guidance on the Biocidal Products Regulation – Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 3.0 April 2018" in house mice ( <i>Mus musculus</i> )	Y	TRIPLAN	2020
██████████	2020	Palatability/efficacy testing of BDCE25V1 bait according to the "Guidance on the Biocidal Products Regulation – Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 3.0 April 2018" in brown rats ( <i>Rattus norvegicus</i> )	Y	TRIPLAN	2020

**Annex 3: Analytical methods residues – active substance**

Brodifacoum
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Date: 25.04.2013

**Methods suitable for the determination of residues (monitoring methods)**

Extract from document IIA of final CAR of brodifacoum.

Table 30: 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	<i>Brodifacoum</i>	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)	<i>Brodifacoum</i>	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)	<i>Brodifacoum</i>	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	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)

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of determination	Reference
						Range	Mean	RSD		
		standard calibration level at 0.3 mg/l								
Cucumber	<i>Brodifacoum</i>	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 <i>Coumatetralyl</i> 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)	<b>IIIA4.3</b> <b>[also</b> <b>IIIA4.2(d)(1) for Meat only]</b>
Wheat			0.01 mg/kg (n=5) 0.1 mg/kg (n=5)			88-126 71-90	107 84	13 9		
Meat			0.01 mg/kg (n=5) 0.1 mg/kg (n=5)			62-86 45-87	73 61	13 29		
Oil-seed rape			0.01 mg/kg (n=5) 0.1 mg/kg (n=5)			75-99 110-134	86 119	10 8		
Lemon			0.01 mg/kg (n=5) 0.1 mg/kg (n=5)			74-93 62-89	84 76	10 13		

**Annex 4: Toxicology and metabolism –active substance**

<b>Brodifacoum</b>
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Threshold Limits and other Values for Human Health Risk Assessment

Date: 31/07/2012

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

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

<b>Classification</b>	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	T+ R27/28 T ;R48/24/25  No specific limit concentrations
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Acute Tox 1 H310 Acute Tox 2 H300 STOT RE Cat 1 H372  No specific limit concentrations

➤ Major change - 2017

<b>Classification</b>	
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Acute Tox 1 H310 Acute Tox 1 H300 Acute Tox 1 H330

**Classification**

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STOT RE Cat 1 H372

Repr 1A H360D

Repr. 1A; H360D: C ≥ 0,003 %

STOT RE 1; H372: C ≥ 0,02 %

STOT RE 2; H373: 0,002 % ≤ C < 0,02 %

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**Annex 5: Toxicology – biocidal product**

<b>FANGA RAT-DICAL TECH</b>
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Date: 31/07/2012

**General information**

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

**Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)**

Rat LD50 oral (OECD 420)	> 2 000 mg/kg bw
Rat LD50 dermal (OECD 402)	> 2 000 mg/kg bw
Rat LC50 inhalation (OECD 403)	No data submitted
Skin irritation (OECD 404)	Non irritant
Eye irritation (OECD 405)	Non irritant
Skin sensitisation (OECD 429; LLNA)	Non sensitizing

**Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)**

Short-term toxicity studies	None
Toxicological data on active substance(s) (not tested with the preparation)	None
Toxicological data on non-active substance(s) (not tested with the preparation)	None
Further toxicological information	None

**Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)**

Directive 1999/45/EC	None
Regulation 1272/2008/EC	None

➤ **Major change - 2017**

**Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)**

Regulation 1272/2008/EC	STOT RE 2 - H373

**Annex 6: Safety for professional operators**

FANGA RAT-DICAL TECH

Date: 31/07/2012

**Exposure assessment**

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

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

	Component	CAS	Actual Dermal Total [mg/kg/d]	Inhalation Exposure [mg/m <sup>3</sup> ]	Model
<b>Control of rats and mice</b>					
Professionnal rat (without gloves)	Brodifacoum	56073-10-0	1.6x10 <sup>-7</sup>	Not applicable	CEFICstudy

Risk assessment– Control of rats and mice

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

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

FANGA RAT-DICAL TECH

General information

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

**Brodifacoum**

Data base for exposure estimation

according to	Appendix: Toxicology and metabolism – active substance/CAR
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Exposure scenarios for intended uses (Annex IIIB, point 6.6 )

Primary exposure	Not applicable
Secondary exposure, acute	Infant ingesting bait
Secondary exposure, chronic	None

**Conclusion:**

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

**Annex 8: Residue behaviour**

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

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

Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*	RI
FANGA RAT-DICAL TECH 0.0025% brodifacoum	House mice ( <i>Mus musculus</i> ) Brown rat ( <i>Rattus norvegicus</i> )	Laboratory test House mice: 10 animals (6 males and 4 females) Brown rat: 10 animals (4 males and 6 females) Intoxication duration: 20 days with daily measurement of mortality and food consumption.	Acclimation: 7 days in individual cage. D0-D5: routine food has been given: 40.0 g for rats, 10.0 g for mice. D6-D20: routine food and tested baits have been given in different feeding dishes. 40.0 g of routine food and 40.0 g of tested baits for rats 10.0 g of routine food and 10.0 g of tested baits for mice.  Food and bait consumption were measured and mortality was observed during 20 days after the first day of intoxication.	The FANGA RAT-DICAL TECH bait containing 25 ppm brodifacoum given to 10 house mice (6 males and 4 females) and to 10 brown rats (4 males, 6 females) during 20 days demonstrated that: <u>For brown rats:</u> The studied bait did not appear as palatable enough for obtaining good performance against brown rat. Mean palatability percentage on brown rat = 2.87 % Mortality percentage on brown rat = 20 % Efficacy can be considered as insufficient for brown rats in the conditions of the test. <u>For house mice:</u> The studied bait did not appear as palatable enough for obtaining good performance against house mouse. Mean palatability percentage on house mouse = 20.15% Mortality percentage on house mouse = 70 %. Efficacy can be considered as moderate for house mice.	██████████ 06 <sup>18</sup> IIIB5.10.2	3
FANGA RAT-DICAL TECH 0.0025% brodifacoum	Brown rats ( <i>Rattus norvegicus</i> )	Laboratory test: Brown rats: 5 males and 5 females.	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,	The FANGA RAT DICAL TECH bait containing 25 ppm brodifacoum given to brown rats (5 males and 5 females) during 4 days has demonstrated:	██████████ Study n°12-TOX024-13 <sup>19</sup> IIIB5.10.2-01	1

<sup>18</sup> De Proft M. 2012 ; Palatability of « FANGA RAT-DICAL TECH » (25 ppm brodifacoum) ready-to-use bait targeting brown rat (*Rattus norvegicus*) and house mouse (*Mus musculus*). Walloon Agricultural Research Centre – Department Pesticide Research, Report n° ROD 2012 06 of 24 May 2012, not GLP, unpublished.

<sup>19</sup> Guicherd A. 2013. Study on the palatability and the efficacy of a maize bait containing 0.0025% brodifacoum in brown rat (*Rattus norvegicus*). Biolytics, Study n° 12-TOX024-13 of 24 January 2013, not GLP (unpublished).

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		Intoxication duration: 4 days with daily measurement of mortality and consumption.	- 50 g per animal of paste bait for the assessment of efficacy during 4 consecutive days with daily consumption measurements. Mortality was observed during 21 days every 24 hours.	- A palatability equivalent to 0.29 (29 %) - Bait consumption half less than the reference item for all rats between day 0 and day 4 - A very good efficacy with a mortality of 100 % in a period from day 5 to day 10		
FANGA RAT-DICAL TECH 0.0025% brodifacoum	House mice ( <i>Mus musculus</i> )	Laboratory test House mice: 10 males and 10 females.  Intoxication duration: 4 days with daily measurement of mortality and consumption.	Acclimatization: 4 days in separate cages (10 males in a cage and 10 females in a second cage) at room temperature. Day 0: reference food and bait biocidal product have been given during 4 consecutive days with daily consumption measurements. Mortality was observed during 21 days every 24 hours or until the death of all animals.	The FANGA RAT-DICAL TECH bait containing 25 ppm brodifacoum given to house mice (10 males and 10 females) during 4 days has demonstrated: - A palatability equivalent to 0.28 (28%) - Not a very good consumption (especially for females) between day 0 and day 4 - A good efficacy with a mortality of 100 % in a period from day 7 to day 11	██████████ Study n° 12-TOX024-9 <sup>20</sup> IIIB5.10.2-02	1
FANGA RAT-DICAL TECH 0.0025% brodifacoum	House mice ( <i>Mus musculus</i> )	Field test: small farm The rodenticide was evaluated using the census baiting technique, which involved the following phases: Pre-treatment census Pre-treatment lag phase Treatment census Post-treatment lag phase Post-treatment census During each assessment the food/bait at each station was weighed and replenished, and the consumption in	Acclimatization: 14 days (150-200 g of semolina per station per day) Treatment : 50 g of maize bait in each lockable bait station (total 10 bait stations) during 11 days Post-baiting: 5 days (150-200 g of semolina per station per day)  Mortality was observed from the first day of intoxication and noted about every 2 days until the end of the trial.	The FANGA RAT-DICAL TECH bait containing 25 ppm brodifacoum given to House mice has demonstrated: The efficacy was total (100%). - Pre-baiting plateau = 140 g/day - Post-baiting = 0 g - Assessed efficacy = 100%  The assessed bait has been very well accepted by house mice and effective and the results are consistent with laboratory ones (100 % efficacy). No secondary poisoning occurred at the baited site.	██████████ Study n° 12-TOX024-16 <sup>21</sup> IIIB5.10-03	1

<sup>20</sup> Guicherd A. 2013. Study on the palatability and efficacy of a 0.0025% brodifacoum corn bait in house mouse (*Mus musculus*). Biolytics, Study n° 12-TOX024-9 of 24 January 2013, not GLP (unpublished).

<sup>21</sup> Guicherd A. 2013. Evaluation of the efficacy of a maize rodenticide (FANGA RAT DICAL TECH) containing 0.0025% brodifacoum for the control of mouse infestation. One trial, 1 site: Rhone, France, 2012-2013. Biolytics, Final Report, Study n° 12-TOX024-16 of 24 January 2013, not GLP (unpublished).

		grams was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites.				
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Annex 9bis: Efficacy of the active substance from its use in the biocidal product 2016

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference
FANGA RAT-DICAL TECH 0.0025% brodifacoum	Black rat ( <i>Rattus rattus</i> )	Field study EPPO PP1/114(2)	<p>Method for recording / scoring effects: daily bait take and tracking score during the trial period</p> <p>The percentage of efficacy of the test product against the rat population was calculated using the following formula:  <math display="block">\% \text{ efficacy} = 100 - \left[ \frac{\text{Post-treatment rat population size index}}{\text{Pre-treatment rat population size index}} \times 100 \right]</math>                     where:                      Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.                      Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.                      - Intervals of examination: every day from 2013-11-06 to 2013-12-27</p>	<p>The trial was set up in an agricultural habitat (chicken breeding stable) showing an adjoining large hangar for the parking of camper vans and equipment storage. In both the buildings rats infestation was signalled by the owner.</p> <p>The site was surveyed and a notable rats presence was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Roof rat (<i>Rattus rattus</i> L.).</p> <p>Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings.</p> <p>In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rat population size during a Pre-treatment census (monitoring of the daily consumption of unpoisoned placebo baits).</p> <p>On the same way it was calculated an index of the rat population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned placebo baits during the Post-treatment phase).</p> <p>According to the results of the present study, FANGA RAT DICAL TECH showed a high acceptance level and provided a complete</p>	<p>██████████ 2010.BCD.SAG13</p>



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				effectiveness (100,0%) against the <i>Rattus rattus</i> population present across the trial site.	
FANGA RAT-DICAL TECH 0.0025% brodifacoum	Brown rat ( <i>Rattus norvegicus</i> )	Laboratory study Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products » Brown rats: 5 males and 5 females. Intoxication duration: 4 days with daily measurement of mortality and consumption.	Acclimatization: 4 days in individual cage at room temperature. Day 0: reference food and bait biocidal product have been given during 4 consecutive days with daily consumption measurements. Mortality was observed during 21 days every 24 hours.	The FANGA RAT-DICAL TECH bait containing 25 ppm brodifacoum given to brown rats (5 males and 5 females) during 4 days according to the Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products » has demonstrated: <ul style="list-style-type: none"> <li>- A palatability equivalent to 0.35</li> <li>- A low consumption between day 0 and day 4</li> <li>- A good efficacy with a mortality of 90% in a period from day 3 to day 12</li> </ul>	15TOX006
FANGA RAT-DICAL TECH 0.0025% brodifacoum	Black rat ( <i>Rattus rattus</i> )	Laboratory study Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products » Black rats: 5 males and 5 females. Intoxication duration: 4 days with daily measurement of mortality and consumption.	Acclimatization: 4 days in individual cage at room temperature. Day 0: reference food and bait biocidal product have been given during 4 consecutive days with daily consumption measurements. Mortality was observed during 21 days every 24 hours.	The FANGA RAT-DICAL TECH bait containing 25 ppm brodifacoum given to black rats (5 males and 5 females) during 4 days according to the Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products » has demonstrated: <ul style="list-style-type: none"> <li>- A palatability equivalent to 0.40</li> <li>- A good consumption between day 0 and day 4</li> <li>- A good efficacy with a mortality of 90% in a period from day 7 to day 11</li> </ul>	15TOX007

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

<p>FANGA RAT-DICAL TECH 0.0025% brodifacoum</p>	<p>Brown rats (<i>Rattus norvegicus</i>)</p>	<p>Field study EPPO PP1/114(2)</p>	<p>Method for recording / scoring effects: daily bait take and tracking score during the trial period The percentage of efficacy of the test product against the rat population was calculated using the following formula: % efficacy = 100 – [ Post-treatment rat population size index/Pre-treatment rat population size index x 100] where: Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census. Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census. - Intervals of examination: every day from 2015-01-02 to 2015-02-12</p>	<p>The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses) in which rats infestation was signalled by the farmer. The farm site was surveyed and a notable rats presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Norway rat (<i>Rattus norvegicus</i> Berk.). Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside or outside the buildings. In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rat population size during a Pre-treatment census (monitoring of the daily consumption of unpoisoned census baits). On the same way it was calculated an index of the rat population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned census baits during the Post-treatment phase). According to the results of the present study, BDM25V1 aged of two years showed a good acceptance level and provided a complete effectiveness (100,0%) against the <i>Rattus norvegicus</i> population present across the trial site.</p>	<p>██████████ 2005.BCD.SAG15</p>
<p>FANGA RAT-DICAL TECH</p>	<p>Black rats (<i>Rattus rattus</i>)</p>	<p>Field study EPPO PP1/114(2)</p>	<p>Method for recording / scoring effects: daily bait</p>	<p>The trial was set up in an agricultural habitat (fodder and equipment warehouses) in</p>	<p>██████████ 2006.BCD.SAG15</p>

<p>0.0025% brodifacoum</p>			<p>take and tracking score during the trial period The percentage of efficacy of the test product against the rat population was calculated using the following formula: % efficacy = 100 – [ Post-treatment rat population size index/Pre-treatment rat population size index x 100] where: Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census. Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census. - Intervals of examination: every day from 2015-01-02 to 2015-02-11</p>	<p>which rats infestation was signalled by the farmer. The farm site was surveyed and a notable rats presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Roof rat (<i>Rattus rattus</i> L.). Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings. In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rat population size during a Pre-treatment census (monitoring of the daily consumption of unpoisoned census baits). On the same way it was calculated an index of the rat population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned census baits during the Post-treatment phase). According to the results of the present study, BDM25V1 aged of two years showed a good acceptance level and provided a complete effectiveness (100,0%) against the <i>Rattus rattus</i> population present across the trial site.</p>	
<p>FANGA RAT-DICAL TECH 0.0025% brodifacoum</p>	<p>House mice (<i>Mus musculus</i>)</p>	<p>Field study EPPO PP1/114(2)</p>	<p>Method for recording / scoring effects: daily bait take and tracking score during the trial period The percentage of efficacy of the test product against</p>	<p>The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses) in which mice infestation was signalled by the farmer. The farm site was surveyed and a notable mice presence over the entire site was</p>	<p>2007.BCD.SAG15</p>

			<p>the rat population was calculated using the following formula:  <math display="block">\% \text{ efficacy} = 100 - \left[ \frac{\text{Post-treatment rat population size index}}{\text{Pre-treatment rat population size index}} \times 100 \right]</math>         where:          Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.          Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.          - Intervals of examination: every day from 2015-01-02 to 2015-02-12</p>	<p>detected. The analysis of the observed runways, footprints and faeces allowed these animals to be identified as belonging to House mouse (<i>Mus musculus</i> L.).          Eight bait-stations and eight tracking patches were set out on the main mice runways which were found inside the buildings.          In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the mice population size during a Pre-treatment census (monitoring of the daily consumption of unpoisoned census baits).          On the same way it was calculated an index of the mice population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned census baits during the Post-treatment phase).          According to the results of the present study, BDM25V1 showed a good acceptance level and provided a complete effectiveness (100,0%) against the <i>Mus musculus</i> population present across the trial site.</p>	
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**Annex 10: Efficacy data submitted in frame of the minor change (2018)**

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
PT 14	Indoor and outdoor around buildings	FANGA RAT-DICAL TECH (BDM25V1)  0.0025 % w/w brodifacoum	Black rat <i>R. rattus</i>	Field test in agricultural habitat 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 rats around the sites.	Acclimatization: 15 days (100 g of mixture of maize grain and poultry/pig feed per station per day) Treatment : 100 g of bait per day in each lockable bait station – total 8 bait stations) during 17 days Post-baiting: 6 days (100 g of mixture of maize grain and poultry/pig feed per day)  Mortality was observed from the first day of intoxication and noted about every 1-4 days until the end of the trial.	Estimated efficacy = 100 %  Pre-baiting plateau = 694.8 g/day  Post-baiting = 0 g  R.I= 1	██████████ 2017 (2079.BCD.SAG17)
PT 14	Indoor and outdoor around buildings	FANGA RAT-DICAL TECH (BDM25V1)  0.0025 % w/w brodifacoum	Black rat <i>R. norvegicus</i>	Field test in agricultural habitat Census baiting technique, which involved the following phases: Pre-treatment census Pre-treatment lag phase Treatment census Post-treatment lag phase Post-treatment census	Acclimatization: 15 days (100 g of mixture of maize grain and poultry/pig feed per station per day) Treatment : 100 g of bait per day in each lockable bait station – total 8 bait stations) during 20 days	Estimated efficacy = 100 %  Pre-baiting plateau = 717 g/day  Post-baiting = 0 g	██████████ 2017 (2078.BCD.SAG17)

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				<p>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 rats around the sites.</p>	<p>Post-baiting: 6 days (100 g of mixture of maize grain and poultry/pig feed per day)</p> <p>Mortality was observed from the first day of intoxication and noted about every 1-4 days until the end of the trial.</p>	R.I= 1	
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Annex 11: Efficacy data submitted in frame of the minor change (2021)

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
PT 14	Indoor and outdoor around buildings	FANGA 5 CEREALES 25 (BDCE25V1)  0.0025 % w/w brodifacoum  Aged bait (39 months)	Norway rat <i>Rattus norvegicus</i>  5 males 5 females	Laboratory choice test	Acclimatization: 7 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 5 consecutive days with daily consumption measurements. Mortality was observed during 21 days every 24 hours or until the death of all animals.	Palatability = 25.7 %  Mortality = 100 %  in a period from day 6 to day 10	██████████ 2020 (BDCE25V1/Rattus norvegicus)  R.I=1
PT 14	Indoor and outdoor around buildings	FANGA 5 CEREALES 25 (BDCE25V1)  0.0025 % w/w brodifacoum  Aged bait (43 months)	Norway rat <i>Rattus norvegicus</i>  Estimated population size: at least 45-55 rats	Field test in agricultural habitat Census baiting technique, which involved the following phases: Pre-treatment census Pre-treatment lag phase Treatment census Post-treatment lag phase Post-treatment census	Acclimatization: 13 days (100 g of mixture of maize grain and poultry/pig feed per station per day) Treatment: 100 g of bait per day in each lockable bait station – total 10 bait stations) during 17 days	Estimated efficacy = 100 %  Pre-baiting plateau = 950,3 g/day  Post-baiting = 0 g	██████████ 2020 (2007.BCD.SAG20)  R.I= 1

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				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 rats around the sites.	Post-baiting: 5 days (100 g of mixture of maize grain and poultry/pig feed per day)  Mortality was observed from the first day of intoxication and noted about every days until the end of the trial.		
PT 14	Indoor and outdoor around buildings	FANGA 5 CEREALES 25 (BDCE25V1)  0.0025 % w/w brodifacoum  Aged bait (43 months)	Black rat <i>Rattus rattus</i>  Estimated population size: at least 60-65 rats	Field test in agricultural habitat 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 rats around the sites.	Acclimatization: 13 days (100 g of mixture of maize grain and poultry/pig feed per station per day) Treatment: 100 g of bait per day in each lockable bait station – total 10 bait stations) during 17 days Post-baiting: 5 days (100 g of mixture of maize grain and poultry/pig feed per day)  Mortality was observed from the first day of intoxication and noted about every days until the end of the trial.	Estimated efficacy = 100 %  Pre-baiting plateau = 940,8 g/day  Post-baiting = 0 g	2020 (2008.BCD.SAG20)  R.I= 1
PT 14	Indoor and outdoor around buildings	FANGA 5 CEREALES 25 (BDCE25V1)  0.0025 % w/w brodifacoum	Black rat <i>Rattus rattus</i>  Estimated population size: at least 55-65 rats	Field test in agricultural habitat Census baiting technique, which involved the following phases: Pre-treatment census Pre-treatment lag phase Treatment census Post-treatment lag phase	Acclimatization: 14 days (100 g of mixture of maize grain and poultry/pig feed per station per day) Treatment: 100 g of bait per day in each lockable bait station –	Estimated efficacy = 100 %  Pre-baiting plateau = 881,8 g/day  Post-baiting = 0 g	2021 (2017.BCD.SAG21)  R.I= 1



**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

		Aged bait (51 months)		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 rats around the sites.	total 12 bait stations) during 15 days Post-baiting: 5 days (100 g of mixture of maize grain and poultry/pig feed per day)  Mortality was observed from the first day of intoxication and noted about every days until the end of the trial.		
PT 14	Indoor and outdoor around buildings	FANGA 5 CEREALES 25 (BDCE25V1)  0.0025 % w/w brodifacoum  Aged bait (39 months)	House mice <i>Mus musculus</i>  5 males 5 females	Laboratory choice test	Acclimatization: 7 days in individual cage at room temperature. Day 0: reference food and bait biocidal product have been given: - 10 g per animal of reference food for the assessment of palatability, - 10 g per animal of biocidal product during 5 consecutive days with daily consumption measurements. Mortality was observed during 20 days every 24 hours or until the death of all animals.	Palatability = 34.5 %  Mortality = 100 %  in a period from day 4 to day 15	██████████ 2020 (BDCE25V1/mouse)  R.I= 1
PT 14	Indoor and outdoor around buildings	FANGA 5 CEREALES 25 (BDCE25V1)  0.0025 % w/w brodifacoum	House mice <i>Mus musculus</i>	Field test in agricultural habitat Census baiting technique, which involved the following phases: Pre-treatment census Pre-treatment lag phase Treatment census	Acclimatization: 14 days (40 g of mixture of maize grain and poultry/pig feed per station per day) Treatment: 40 g of bait per day in each lockable bait station –	Estimated efficacy = 100 %  Pre-baiting plateau = 336,8 g/day	██████████ 2020 (2009.BCD.SAG20)  R.I= 1

**Product Assessment Report – FANGA 5 CEREALES 25 - Brodifacoum**

		Aged bait (43 months)		<p>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.</p>	<p>total 10 bait stations) during 18 days          Post-baiting: 5 days (40 g of mixture of maize grain and poultry/pig feed per day)           Mortality was observed from the first day of intoxication and noted about every days until the end of the trial.</p>	<p>Post-baiting = 0 g</p>	
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