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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

FANGA B + BLOC P

Product type 14

Brodifacoum

Case Number in R4BP: BC-YR018673-07

Evaluating Competent Authority: FR

Date: January 2017

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1 CONCLUSION

Conclusion on the physical, chemical and technical properties of the product

FANGA B+ BLOC P is a blue wax block (weight of blocks: 4, 20, 25, 30, 40, 50, 100 g) ready-to-use rodenticide.

FANGA B+ BLOC P is not flammable, not autoflammable (self ignition temperature: 253.7°C), has no explosive properties and no oxidizing properties. The product contains more than 10% of H304 compounds. Nevertheless, as the product is a solid, it is not classified for physico-chemical properties.

No change appeared in the appearance of the biocidal product or the packaging after storage procedures for 8 weeks at 40 ± 2°C. No significant change was observed in the content of the active substance after the accelerated storage procedure at 40 °C ± 2 °C for 8 weeks in transparent PE or PP bags, in white opaque PP bucket with bubble wrap and in cardboard box with bubble wrap. The product must be stored at a temperature below 40°C.

A long term storage stability study in commercial packaging is ongoing. Results are required in post authorization in a time limit of 2 years (end expected: November 2018). As the results of the accelerated storage are acceptable, a shelf life of 2 years can be granted. If a shelf life of 4 years is claimed, the applicant should submit a dossier of minor change.

The active substance is sensitive to light. No test has been provided. Therefore, the product must be stored away from light, as it is preconized on the label.

Analytical methods for the determination of brodifacoum in the product FANGA B+ BLOC P has been provided and validated according to SANCO3030/99/rev.4. The applicant has a letter of access of Activa for analytical methods used for the determinaiton of the active substance in food, soil, water and blood.

Conclusion on efficacy of the product

French competent authorities (FR CA) assessed that the product FANGA B+ BLOC P has shown a sufficient efficacy for the control of *Rattus norvegicus, Rattus rattus* and *Mus musculus* in and around building, in open areas, in waste dumps, landfills and in sewers (only *Rattus norvegicus*) but only on the highest application rates claimed (40 per baiting point for house mice and 200 g per baiting point for rats. Indeed, the efficacy tests presented in the dossier were performed at 40 g per baiting point for house mice and 200 g per baiting point for rats (*Rattus rattus* and *Rattus norvegicus*).

The applicant claims a maximum storage duration of 4 years. But the product does not contain preservative and the efficacy tests have been performed with the product (2 years aged maximum). Then the efficacy is not demonstrated for products aged more than 2 years.

Furthermore, no test with a product older than 5 months has been submitted for *Rattus rattus*. A maximum duration of storage of 2 years is proposed. A new field efficacy will have to be provided in support of the authorisation, within two years after authorisation to confirm the efficacy of the 2 years product on this species.

The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management every two years.

Conclusion for Human Health

Based on the risk assessment of the active substance, the risk for professional and non-professional users resulting from the intended use is acceptable for FANGA B+ BLOC P for the control of rats and mice.

Risk of secondary poisoning to infants and children is considered as relevant. Therefore, even if FANGA B+ BLOC P contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children.

Conclusion on indirect exposure via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

Conclusion for environment and ecotoxicolgy

No studies were conducted with the product FANGA B+ BLOC P 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 non-professionals and for the use in and around building 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.

The French Competent Authority in charge of delivring biocidal product authroization also considers that the environmental risk is limited in strict compliance with the specific use instructions of rodenticidal baits and the use restrictions to reduce the risk for primary and secondary poisoning for the following uses:

- around the buidings by non-professionals ;
- the use in open area by professionals ;
- the use in waste dump by professionals ;
- the use in sewers by professionnals

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

In the course of the evaluation of FANGA B+ BLOC P, one manufacturer of the product has been added.

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
FANGA B+ BLOC P	France

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	TRIPLAN SA
	Address	BP 258 LA POSTE FRANCAISE AD500 ANDORRA LA VELLA ANDORRA
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturers of the products of the family

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

Name of manufacturer	SARL LFT SETA
Address of manufacturer	CHATEAU DE PUECHASSAU 81140 BROUSSE-LAUTREC FRANCE
Location of manufacturing sites	CHATEAU DE PUECHASSAU 81140 BROUSSE-LAUTREC FRANCE

Name of manufacturer	SOFIP
Address of manufacturer	CHEZ EDIALUX / ZA MACON EST 01750 REPLONGES FRANCE
Location of manufacturing sites	ZA MACON EST 01750 REPLONGES FRANCE

Name of manufacturer	INDUSTRIAL CHIMICA SRL

1 Please fill in here the identifying product name from R4BP.

Address of manufacturer	VIA SORGAGLIA 40 35020 ARRE ITALY
Location of manufacturing sites	VIA SORGAGLIA 40 35020 ARRE ITALY

Name of manufacturer	RATOUCY SAS
Address of manufacturer	29 AVENUE DE LA FORET - LOOZE - BP145 89303 JOIGNY FRANCE
Location of manufacturing sites	29 AVENUE DE LA FORET - LOOZE - BP145 89303 JOIGNY FRANCE

Name of manufacturer	LARC
Address of manufacturer	ZA DE KERAMPAOU 29140 MELGVEN FRANCE
Location of manufacturing sites	ZA DE KERAMPAOU 29140 MELGVEN FRANCE

Name of manufacturer	SALOMEZ
Address of manufacturer	ZA AV. DU GENERAL DE GAULLE 89130 TOUCY FRANCE
Location of manufacturing sites	ZA AV. DU GENERAL DE GAULLE 89130 TOUCY FRANCE

Name of manufacturer	NOXIMA
Address of manufacturer	CARREFOUR JEAN MONNET - LACROIX SAINT OUEN 60201 COMPIEGNE FRANCE
Location of manufacturing sites	CARREFOUR JEAN MONNET - LACROIX SAINT OUEN 60201 COMPIEGNE FRANCE

2.1.1.4 Manufacturer of the active substance

Active substance	Brodifacoum
Name of manufacturer	ACTIVA / TEZZA
Address of manufacturer	VIA FELTRE 32 20132 MILAN ITALY
Location of manufacturing sites	VIA TRE PONTI 22 37050 S. MARIA DI ZEVIO ITALY

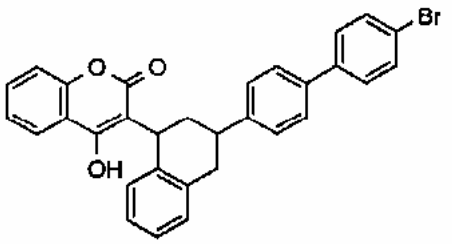
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Brodifacoum
IUPAC or EC name	3-[3-(4'-bromobiphenyl- 4-yl)-1,2,3,4-tetrahydro -1-napthyl]-4-hydroxycoumarin
EC number	259-980-5
CAS number	56073-10-0
Index number in Annex VI of CLP	
Minimum purity / content	950 g/kg
Structural formula	

2.1.2.2 Candidate(s) for substitution

As agreed in AC meeting, the comparative assessment for AVK rodenticides is performed at the European level.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[2]

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-(4'-bromobiphenyl- 4-yl)-1,2,3,4-tetrahydro -1-napthyl]-4-hydroxycoumarin	Active substance	56073-10-0	259-980-5	0.0012
		Non-active substance[3]			

Co-formulants composition of the product is confidential and is presented in a confidential annex.

2.1.2.4 Information on technical equivalence

No relevant since the origin is already recognized at EU level.

2.1.2.5 Information on the substance(s) of concern

The biocidal product contains no substances of concern.

2.1.2.6 Type of formulation

RB - Bait (ready for use)

2.1.3 Hazard and precautionary statements[4]

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

Classification	
Hazard category	-
Hazard statement	-
Labelling	
Signal words	-
Hazard statements	-

2 Please delete as appropriate.

3 Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

4 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Classification	
Precautionary statements	-
Note	**-**

There are 2 compounds classified as dangerous for the environment in the products FANGA B+ BLOC P. Nevertheless none of these substances contribute individually to the classification of the biocidal product FANGA B+ BLOC P because their individual concentrations are lower than the limits specified under the Regulation (EC) 1272/2008.

2.1.4 Authorised use(s)

2.1.4.1 Use description[5]

Table 1. Use # 1 – Professional users

Product Type	14
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	*Rattus norvegicus* (Brown rat) *Rattus rattus* (Roof rat, House rat) *Mus musculus* (House mouse) Juveniles Adults
Field of use	Inside and outside buldings, open areas, waste dumps, landfills and in sewers
Application method(s)	covered application bait boxes other bait stations
Application rate(s) and frequency	Rats: 200 g every 5 to 10 meter House Mice: 40 g every 1 to 2 meter Bait points should be controlled and resupplied during treatment period: - 3 days after the first application then weekly for use in and around building, and in open areas. - 1 week after the first application then monthly for use in waste dumps, landfills and in sewers. Resupply as long as the bait is consumed. The mean biocidal action period of FANGA B + BLOC P is 1 to 9 days.
Category(ies) of users	Professionals
Pack sizes and packaging material	The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:

5 Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

	- Bag (paper bags several layers with one or without plastic film in low density polyethylene) (5;10;15;20;25kg) - High density polyethylene bucket (5;10;15;18;20kg) - Carton box (5;10;12;20;50kg) The product is also supplied in loose in: - Low density polyethylene or polypropylene sachet (100;200;300;400;500;600;700;800;900;1000g) and packed in carton box (5;10;12;15;18;20kg) - Bag (paper bags several layers with one or without plastic film in low density polyethylene (5;10;15;20;25kg) - High density polyethylene bucket (5;10;15;18;20;25kg) Carton box (5;10;12;15;20;25;50kg)

2.1.4.2 Use-specific instructions for use[6]

- Adapt the number of bait stations to the infestation level.
- Inspect and resupply the bait stations:
  - 3 days after the first application then weekly in and around buildings and in open areas.
  - 1 week after the first application then monthly for use in waste dumps, landfills and in sewers.
- Remove all bait points after the end of the treatment.
- The amount of bait per bait point and distances between bait points must be respected.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.
- To avoid resistance:
  - The treatment has to be alternated with other kinds of active substances having different modes of action.
  - Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures.
  - The level of efficacy have to be monitored (periodic check), and the case of reduced efficacy has to be investigated for possible evidence of resistance.
  - Do not use the product in areas where resistance is suspected or established.

2.1.4.3 Use-specific risk mitigation measures

- 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.
- 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 professional users, covered bait stations could be used. These stations must be placed only in areas not accessible to the general public and non-target animals.

6 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

- Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Use in bait boxes or in bait stations
- Place the bait boxes and bait stations in area non submersible
- 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.

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

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

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

2.1.4.7 Use description[7]

Table 2. Use # 1 – Non professional users

Product Type	14
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	*Rattus norvegicus* (Brown rat) *Rattus rattus* (Roof rat, House rat) *Mus musculus* (House mouse) Juveniles Adults
Field of use	Indoor use, aroung the buildings
Application method(s)	bait boxes
Application rate(s) and frequency	Rats: 200 g every 5 to 10 meter House Mice: 40 g every 1 to 2 meter Bait points should be controlled and resupplied during treatment period: - 3 days after the first application then weekly

7 Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

	Resupply as long as the bait is consumed. The mean action period of biocidal effect of FANGA B + BLOC P is 1 to 9 days.
Category(ies) of users	Non professionals
Pack sizes and packaging material	The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in: - High density polyethylene bucket , carton box, metal box without lacquer and high density polyethylene container (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 already filled or not, in polyethylene terephtalate/polypropylene/high density polyethylene/polychloride vinyl) with a capacity of 200g

2.1.4.8 Use-specific instructions for use[8]

- Adapt the number of bait stations to the infestation level.
- Inspect and resupply the bait stations, 3 days after the first application then weekly
- Remove all bait points after the end of the treatment.
- The amount of bait per bait point and distances between bait points must be respected.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.

2.1.4.9 Use-specific risk mitigation measures

- Do not open the sachets.
- Use only in tamper-resistant boxes.
- Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Place the bait boxes and bait stations in area non submersible
- 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.
- Never wash the bait boxes with water

8 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

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

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

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

2.1.5 General directions for use

2.1.5.1 Instructions for use[9]

2.1.5.2 Risk mitigation measures

Do not place tamper-resistant bait boxes and covered bait stations on surfaces in contact with food, feed or drinks and beverages.

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

If inhaled: breathe fresh air and keep at rest. If a contact occurs with skin: Remove contaminated clothes and wash skin with soap and rinse copiously with water. Do not use solvents or thinners. If a contact occurs with eyes: Wash copiously under a trickle of water (tepid if possible) for several minutes, keeping eyelids open under the trickle of water. If swallowed, seek medical advice immediately and show this container or label. Do not induce vomiting. Whatever the quantity of the product ingested, do not eat and do not drink. In case of emergency, contact 112. Note to doctor: the product FANGA B+ BLOC P contains an anticoagulant-rodenticide, treatment with vitamin K1 could be needed for a long time.

9 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.5.4 Instructions for safe disposal of the product and its packaging

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

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

Shelf life: 2 years
The product must be stored below 40°C.
Store away from light

2.1.6 Other information

- Field tests against *Rattus rattus* performed with a 2 years aged product must be submitted to support the storage duration of 2 years, within two year after authorisation.
- The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance brodifacoum, and resistance strategies management must be put in place. Results of the resistance monitoring must be submitted to the Competent Authorities (CA) or other appointed bodies involved in resistance management every 2 years.
- Results of the long term storage stability study in commercial packaging are required in post authorization in a time limit of 2 years

2.1.7 Packaging of the biocidal product

Professional
The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:

- Bag (paper bags several layers with one or without plastic film in low density polyethylene) (5;10;15;20;25kg)
- High density polyethylene bucket (5;10;15;18;20kg)
- Carton box (5;10;12;20;50kg)

The product is also supplied in loose in:

- Low density polyethylene or polypropylene sachet (100;200;300;400;500;600;700;800;900;1000g) and packed in carton box (5;10;12;15;18;20kg)
- Bag (paper bags several layers with one or without plastic film in low density polyethylene (5;10;15;20;25kg)
- High density polyethylene bucket (5;10;15;18;20;25kg)
- Carton box (5;10;12;15;20;25;50kg)

Non professional
The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:

- High density polyethylene bucket , carton box, metal box without lacquer and high density polyethylene container (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 already filled or not, in polyethylene terephtalate/polypropylene/high density polyethylene/polychloride vinyl) with a capacity of 200g

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Identity, physicochemical and analytical method data

Physico-chemical properties studies and analytical methods on the biocidal product FANGA B+ BLOC P were provided by TRIPLAN.

Efficacy data

The following efficacy studies were submitted:

- A free-choice laboratory test was carried out with house mice (***Mus musculus***), with exposure to a 3 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum) for 4 days.
- A free-choice laboratory test was carried out with brown rats (***Rattus norvegicus***), with exposure to a 6 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum) for 4 days.
- A free-choice laboratory test was carried out with black rats (***Rattus rattus***), with exposure to a 6 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum) for 4 days.
- A field test was carried out with brown rats (***Rattus norvegicus***), with exposure to a 5 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum).
- A field test was carried out with black rats (***Rattus rattus***), with exposure to a 5 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum).
- A field test was carried out with house mice (***Mus musculus***), with exposure to a 5 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum).
- A free choice laboratory test was carried out with brown rats (*Rattus norvegicus*), with exposure to a 2 years aged formulation of the product **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum) stored in damp conditions (80 % relative humidity, 30 -35 °C) for 5 days
- A field test was carried out with house mice (***Mus musculus***), with exposure to 21 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum)

Toxicology data

Acute oral and dermal toxicity, skin and eye irritation and skin sensitisation studies have been realized with the product FANGA BLOC SP PRO, a block formulation containing 0.005% of brodifacoum. The compositions of FANGA BLOC SP PRO and FANGA B+ BLOC P are considered similar.

Residues data

No specific residue data were submitted in the context of this dossier. The product FANGA B+ BLOC P is intended to be used in bait station indoor and outdoor. It will not get in contact with food or feed. Residue in food or feed are not expected. Considering the intended uses no data is required.

Ecotoxicology data

None

2.1.8.2 Access to documentation

A letter of access on the annex II data of the active substance has been provided by ACTIVA to TRIPLAN.

2.2 Assessment of the biocidal product

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

Table 3. Intended use # 1 – Professional and non professional users [10]

Product Type(s)	PT14-Rodenticides
Where relevant, an exact description of the authorised use	FANGA B + BLOC P is intended to be used as a rodenticide against wild mice, brown rats and black rats in and around buildings, open areas, waste dumps, landfills and sewers by professional users. It is also intended to be used in and around buildings and open areas by non-professional users. Baits are placed in bait boxes or in secured bait stations.
Target organism (including development stage)	*Rattus rattus*, common name: roof rat (syn.), development stage: adults/juveniles *Rattus norvegicus*, common name: brown rat, development stage: adults/juveniles *Mus musculus*, common name: house mouse, development stage: adults/juveniles
Field of use	Indoor and outdoor
Application method(s)	
Application rate(s) and frequency	Rats : 180-200 g/secured bait point (5-10 meters between 2 bait points) 4 refilling of bait stations over 28 days Interval between applications (min) : one week Mice : 30-40 g/secured bait point (1-2 meters between 2 bait points) 4 refilling of bait stations over 28 days Interval between applications (min) : one week
Category(ies) of user(s)	Professional and non professional users
Pack sizes and packaging material	PROFESSIONALS FANGA B+ BLOC P is conditionned in low density polyethylene or polypropylene sachets (4 ; 20 ; 25 ; 30 ; 40 ; 50 ; 100g) and packed in : - Paper bags with or without a low density polyethylene lining (5 ; 10 ; 15 ; 18 ; 20kg) The product is also sold in bulk in: - Low density prolyethylene or polypropylene sachets (100 ; 200 ; 300 ; 400 ; 500 ; 600 ; 700 ; 800 ; 900 ; 1000g) and in carboard boxes (5 ; 10 ; 12 ; 15 ; 18 ; 20kg) - Paper bags with or without low density polyethylene density (5 ; 10 ; 15 ; 20 ; 25kg) - High density polyethylene seals (5 ; 10 ; 15 ; 18 ; 20 ; 25kg) - Cardboard boxes (5 ; 10 ; 12 ; 15 ; 20 ; 25 ; 50kg)

10 Copy this section as many times as necessary (one table per use).

	NON PROFESSIONALS FANGA B+ BLOC P is conditionned in polyethylene or polypropylene sachets (4 ; 20 ; 25 ; 30 ; 40 ; 50 ; 100g) and packed in : - Low density polyethylene seals, cardboard boxes, metallic boxes without internal varnish, high density polyethylene bottles (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) Pre-filled or not pre-filled bait stations in terephthalate polyethylene/ polypropylene/ high density polyethylene/ chlorure polyvinyl chloride of 200g

2.2.2 Physical, chemical and technical properties

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains 0.0012% of pure brodifacoum (0.001209% technical brodifacoum).

The product does not contain PT6 conservative.

Formulation type: ready to use block bait

Hydrocarbon and H304 co-formulant content: ≥10%.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
Physical state at 20 °C and 101.3 kPa	Visual determination		Blocks containing cereal grain	Acceptable.	Demangel B, 2015 Report 15-920010-011
Colour at 20 °C and 101.3 kPa			blue		
Odour at 20 °C and 101.3 kPa					
Acidity / alkalinity	CIPAC MT 75.3	DBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	Before the accelerated storage procedure The mean pH value of the test item at 1% w/v in standard water D was: 6.32 at 19.7 °C after 1 min. 6.32 at 19.8 °C after 2 min.	Acceptable	Demangel B, 2015 Report 15-920010-011
Relative density / bulk density	OECD109, EU method A3	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	The mean relative density of the test item was : D20/4°C = 1.221 ± 0.002.	Acceptable	Demangel B, 2015 Report 14-920010-006
Storage stability test – **accelerated storage 8 weeks at 40°C**	CIPAC MT 46.3 Analytical method validated (report 14-920010-009) CIPAC MT 193	BDBP12V1 (Trade name: FANGA B+ BLOC P) Batch: LLC 14-28-3	packaging: transparent PE bag in a cardboard box, transparent PP bags PRODUCT APPEARANCE : Blue blocks - Changes in colour: no - Changes in odour: no - Changes in clarity: no - Changes in texture: no	Acceptable. The product is stable after 8 weeks at 40°C in PE and PP bags. The product must be stored at a temperature below 40°C.	Demangel B, 2015 14-920010-007 amended

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			CONTAINER APPEARANCE -Transparent PE bag in a cardboard box Description of changes: no change - Transparent PP bag Description of changes: no change MASS CHANGES - Initial total mass (product + packaging): Transparent PE bag in a cardboard box (packaging internal number : 3): 471.8 g Transparent PP bag (packaging internal number: 11) : 20.6 g Transparent PP bag (packaging internal number: 12) : 20.0 g - Mass after storage (product + packaging): Transparent PE bag in a cardboard box (packaging internal number : 3): 452.9 g Difference of weight = -4% Transparent PP bag (packaging internal number: 11) : 19.6 g Difference of weight = -4.9% Transparent PP bag (packaging internal number: 12) : 19.1 g Difference of weight = -4.5%		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			CHANGE IN ACTIVE INGREDIENTS Results: - Before the accelerated storage procedure: Mean: 0.001264% w/w - After the accelerated storage procedure * For the test item in transparent PE bag in a cardboard box: Mean: 0.001250% w/w Deviation from T=0 value: -1.1% * For the test item in transparent PP bag Mean: 0.001258% w/w Deviation from T=0 value: -0.5% ATTRITION RESISTANCE Before the accelerated storage procedure The attrition of tablets was 99.2%. After the accelerated storage procedure The attrition of tablets was 99.4%.		
	CIPAC MT 46.3 Analytical method validated	BDBP12V1 (Trade name: FANGA B+ BLOC P)	PRODUCT APPEARANCE Before storage at 40°C for 8 weeks: Blue blocks containing cereal grains	Acceptable. The product is stable after 8 weeks at 40°C in PP bucket and	Demangel B, 2015 Report 15-920010-011

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
	(report 14-920010-009) CIPAC MT 75.3	Batch: LLC 14-28-3	After storage at 40°C for 8 weeks: - Changes in colour: no change - Changes in odour: no change - Changes in texture: no change CONTAINER APPEARANCE Before storage at 40°C for 8 weeks: Blue blocks containing cereal grains in white opaque PP bucket with bubble wrap (packaging internal number: 2) Blue blocks containing cereal grains in cardboard box with bubble wrap (packaging internal number: 3) - Description of changes: no change. MASS CHANGES - Before the accelerated storage procedure Blue blocks containing cereal grains White opaque PP bucket with bubble wrap Weight: 556g - after the accelerated storage procedure Blue blocks containing cereal grains White opaque PP bucket with bubble wrap	cardboard box. The product must be stored at a temperature below 40°C. Attrition resistance has been performed in the previous study (Demangel B, 2015 14-920010-007 amended).	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			Weight: 552.7g (-0.7%) - Before the accelerated storage procedure Blue blocks containing cereal grains Cardboard box with bubble wrap Weight: 381.7g - after the accelerated storage procedure Blue blocks containing cereal grains Cardboard box with bubble wrap Weight: 373g (-2.3%) CHANGE IN ACTIVE INGREDIENTS Results: - Before the accelerated storage procedure Blue blocks containing cereal grains in white opaque PP bucket with bubble wrap Content of active ingredient: mean 0.0013% Blue blocks containing cereal grains in cardboard box with bubble wrap Content of active ingredient: mean 0.0013% - After the accelerated storage		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			procedure Blue blocks containing cereal grains in white opaque PP bucket with bubble wrap Content of active ingredient: mean 0.0013% - deviation from T0 value: 0.0% Blue blocks containing cereal grains in cardboard box with bubble wrap Content of active ingredient: mean 0.0013% - deviation from T0 value: 0.0% pH Before the accelerated storage procedure The mean pH value of the test item at 1% w/v in standard water D was: 6.32 at 19.7 °C after 1 min. 6.32 at 19.8 °C after 2 min. After the accelerated storage procedure The mean pH value of the test item at 1% w/v in standard water D was: 5.24 at 21.2 °C after 1 min. 5.32 at 21.4 °C after 2 min.		
Storage stability test – **long term storage at ambient temperature**			Studies on-going since November 2014:	Results of the shelf life studies are required in post	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			N°14-920010-008: shelf life 2 years at 20°C N°14-920010-010: 3 years at 20°C N°14-920010-011: 4 years at 20°C	authorization in a time limit of 2 years. As the results of the accelerated storage are acceptable, a shelf life of 2 years is proposed. If a shelf life of 4 years is claimed, the applicant should submit of dossier of minor change.	
Storage stability test – **low temperature stability test for liquids**			Not applicable	Not relevant for solid	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			All packaging are opaque. Therefore, the effect of light has not been studied.	Acceptable for cardboard box . However, plastic packaging are not barrier to light. Moreover the active substance is sensitive to light (DT50<1 day; photolysis in water). Nevertheless, it is mentioned on the label that the product must be store away from light. No further data are required.	
Effects on content of the active substance and technical			No effect of temperature has been noticed during the accelerated storage stability study.	Acceptable. The product is stable after 8 weeks at 40°C.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
characteristics of the biocidal product – **temperature and humidity**					
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			According to the accelerated storage stability studies, the product is compatible with carton and polyethylene/polypropylene packaging.	Acceptable.	
Wettability			Not applicable	Not relevant	
Suspensibility, spontaneity and dispersion stability			Not applicable	Not relevant	
Wet sieve analysis and dry sieve test			Not applicable	Not relevant	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable	Not relevant	
Disintegration time			Not applicable	Not relevant	
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 193	BDBP12V1 (Trade name: FANGA B+ BLOC P) Batch: LLC 14-28-3	Before the accelerated storage procedure The attrition of tablets was 0.8%. After the accelerated storage procedure The attrition of tablets was 0.6%.	Acceptable. Dust content has not been studied. Nevertheless, according to the composition and the type of product (block bait), this test is not relevant.	Demangel B, 2015 14-920010-007 amended
Persistent foaming			Not applicable	Not relevant	
Flowability/Pourability/ Dustability			Not applicable	Not relevant	
Burning rate — smoke			Not applicable	Not relevant	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
generators					
Burning completeness — smoke generators			Not applicable	Not relevant	
Composition of smoke — smoke generators			Not applicable	Not relevant	
Spraying pattern — aerosols			Not applicable	Not relevant	
Physical compatibility			Not applicable. The product is not intended to be mixed with others products.	Not relevant	
Chemical compatibility			Not applicable. The product is not intended to be mixed with others products.	Not relevant	
Degree of dissolution and dilution stability			Not applicable	Not relevant	
Surface tension			Not applicable	Not relevant	
Viscosity			Not applicable	Not relevant	

Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
Explosives	DSC	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	A test was performed to determine if the product presents exothermic reaction during DSC analysis. During the first phase, one exothermic peak was observed at 244.2 °C. The exothermic reaction energy is less than 500 J/g (256.8J/g) and the onset of exothermic decomposition is below 500°C. The test item is not expected to get explosive properties.	Acceptable. The product is not explosive.	Demangel B, 2015 Report 14-920010-006
Flammable gases			Not applicable	Not applicable	
Flammable aerosols			Not applicable	Not applicable	
Oxidising gases			Not applicable	Not applicable	
Gases under pressure			Not applicable	Not applicable	
Flammable liquids			Not applicable	Not applicable	
Flammable solids	United Nations Recommendations on the Transport of Dangerous Goods Manual of tests and Criteria Fifth revised edition (2010) Test N.1 (Part III, Section 33.2.1.4)	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	Type of test item Block (The test item was grated) Application of the flame 43 s for the assay No. 1 and 35 s for the assay No. 2 4.1.2. Assay No. 1 From 43 s to 1 min 42 s, the test item ignited and a propagation of the combustion was observed over about 1 cm. Neither ignition, nor propagation was observed after 1 min 42 s. Assay No. 2 From 35 s to 1 min 29 s, the test item ignited and a propagation of the combustion was observed over about 1.5 cm. Neither ignition, nor propagation was observed after 1 min 29 s. Main test Taking into account the results obtained during the preliminary test, no main test was performed. Since the burn rate is below 2.2mm/s, the test item was not classified as a flammable solid of Division	Acceptable. The product is not highly flammable.	Demangel B, 2015 Report 14-920010-006

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			4.1 and thus was not assigned to any packing group, under the experimental conditions used.		
Self-reactive substances and mixtures			According to Regulation (EC) No.1272/2008, homogeneous mixtures of organic substances should be considered for classification in this hazard class unless their exothermic decomposition energy is less than 300 J/g. As the exothermic decomposition is below this limit, the product is not a self reactive mixture.	Acceptable.	
Pyrophoric liquids			Not applicable	Not applicable	
Pyrophoric solids			Not required as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature.	Acceptable.	
Self-heating substances and mixtures	EEC A16	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	No test was provided. Nevertheless, regarding the composition, the product is not expected to heat with air without additional energy.	Acceptable The product is not a self heating mixture.	Demangel B, 2015 Report 14-920010-006
Substances and mixtures which in contact with water emit flammable gases			The product does not contain compounds which are suspected to emit gases in contact with water.	Acceptable	
Oxidising liquids			Not applicable	Not applicable	
Oxidising solids	United Nations Recommendations on the Transport of Dangerous Goods Manual of	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC	Preparation of the mixtures 30.0 g ± 0.1 g mixtures were prepared with the following proportions: Test item : mixture item/cellulose (4:1, 1:1) reference: potassium bromate/cellulose (3:7, 2:3, 3:2)	Acceptable. The product has no oxidizing properties.	Demangel B, 2015 Report 14-920010-006

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
	tests and Criteria Fifth revised edition (2009) Test O.1 (Part III, Section 34.4.1)	14-28-3	Five assays were performed with each mixture, and the mean time of the main reaction was calculated. The mean time of reaction with the test item / cellulose mixture in proportions 4:1 was higher than the mean time of reaction with the reference item / cellulose mixture in proportions 3:7. Therefore, the test item was not considered as an oxidising solid of Division 5.1 and thus was not assigned to any packing group.		
Organic peroxides			Not applicable	Not applicable	
Corrosive to metals					
Auto-ignition temperatures of products (liquids and gases)	EEC A16	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	The self-ignition temperature of the test item was 253.7°C.	Acceptable. The product is not auto-flammable up to 253.7°C.	Demangel B, 2015 Report 14-920010-006
Relative self-ignition temperature for solids	EU A16	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	The self-ignition temperature of the test item was 253.7 °C	Acceptable. The product is not auto-flammable up to 253.7°C.	Demangel B, 2015 Report 14-920010-006
Dust explosion hazard			Not applicable	Not relevant	

Conclusion on the physical, chemical and technical properties of the product
FANGA B+ BLOC P is a blue wax block (weight of blocks: 4, 20, 25, 30, 40, 50, 100 g) ready-to-use rodenticide. FANGA B+ BLOC P is not flammable, not autoflammable (self ignition temperature: 253.7°C), has no explosive properties and no oxidizing properties. The product contains more than 10% of H304 compounds. Nevertheless, as the product is a solid, it is not classified for physico-chemical properties. No change appeared in the appearance of the biocidal product or the packaging after storage procedures for 8 weeks at 40 ± 2°C. No significant change was observed in the content of the active substance after the accelerated storage procedure at 40 °C ± 2 °C for 8 weeks in transparent PE or PP bags, in white opaque PP bucket with bubble wrap and in cardboard box with bubble wrap. The product must be stored at a temperature below 40°C. A long term storage stability study in commercial packaging is ongoing. Results are required in post authorization in a time limit of 2 years (end expected: November 2018). As results of the accelerated storage are acceptable, a shelf life of 2 years can be granted. The active substance is sensitive to light. No test has been provided. Therefore, the product must be stored away from light, as it is preconized on the label. **Labelling mention:** shelf life: 2 years. store away from light. The product must be stored below 40°C.

2.2.3 Physical hazards and respective characteristics

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Comments**	**Reference**
Explosives	DSC	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	A test was performed to determine if the product presents exothermic reaction during DSC analysis. During the first phase, one exothermic peak was observed at 244.2 °C. The exothermic reaction energy is less than 500 J/g (256.8J/g) and the onset of exothermic decomposition is below 500°C. The test item is not expected to get explosive properties.	Acceptable. The product is not explosive.	Demangel B, 2015 Report 14-920010-006
Flammable gases			Not applicable	Not applicable	
Flammable aerosols			Not applicable	Not applicable	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
Oxidising gases			Not applicable	Not applicable	
Gases under pressure			Not applicable	Not applicable	
Flammable liquids			Not applicable	Not applicable	
Flammable solids	United Nations Recommendations on the Transport of Dangerous Goods Manual of tests and Criteria Fifth revised edition (2010) Test N.1 (Part III, Section 33.2.1.4)	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	Type of test item Block (The test item was grated) Application of the flame 43 s for the assay No. 1 and 35 s for the assay No. 2 4.1.2. Assay No. 1 From 43 s to 1 min 42 s, the test item ignited and a propagation of the combustion was observed over about 1 cm. Neither ignition, nor propagation was observed after 1 min 42 s. Assay No. 2 From 35 s to 1 min 29 s, the test item ignited and a propagation of the combustion was observed over about 1.5 cm. Neither ignition, nor propagation was observed after 1 min 29 s. Main test Taking into account the results obtained during the preliminary test, no main test was performed. Since the burn rate is below 2.2mm/s, the test item was not classified as a flammable solid of Division 4.1 and thus was not assigned to any packing group, under the experimental conditions used.	Acceptable. The product is not highly flammable.	Demangel B, 2015 Report 14-920010-006
Self-reactive substances and mixtures			According to Regulation (EC) No.1272/2008, homogeneous mixtures of organic substances	Acceptable.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			should be considered for classification in this hazard class unless their exothermic decomposition energy is less than 300 J/g. As the exothermic decomposition is below this limit, the product is not a self reactive mixture.		
Pyrophoric liquids			Not applicable	Not applicable	
Pyrophoric solids			Not required as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature.	Acceptable.	
Self-heating substances and mixtures	EEC A16	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	No test was provided. Nevertheless, regarding the composition, the product is not expected to heat with air without additional energy.	Acceptable The product is not a self heating mixture.	Demangel B, 2015 Report 14-920010-006
Substances and mixtures which in contact with water emit flammable gases			The product does not contain compounds which are suspected to emit gases in contact with water.	Acceptable	
Oxidising liquids			Not applicable	Not applicable	
Oxidising solids	United Nations Recommendations on the Transport of Dangerous Goods Manual of tests and Criteria Fifth revised edition (2009)	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	Preparation of the mixtures 30.0 g ± 0.1 g mixtures were prepared with the following proportions: Test item : mixture item/cellulose (4:1, 1:1) reference: potassium bromate/cellulose (3:7, 2:3, 3:2) Five assays were performed with each mixture, and the mean time of the main	Acceptable. The product has no oxidizing properties.	Demangel B, 2015 Report 14-920010-006

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
	Test O.1 (Part III, Section 34.4.1)		reaction was calculated. The mean time of reaction with the test item / cellulose mixture in proportions 4:1 was higher than the mean time of reaction with the reference item / cellulose mixture in proportions 3:7. Therefore, the test item was not considered as an oxidising solid of Division 5.1 and thus was not assigned to any packing group.		
Organic peroxides			Not applicable	Not applicable	
Corrosive to metals					
Auto-ignition temperatures of products (liquids and gases)	EEC A16	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	The self-ignition temperature of the test item was 253.7°C.	Acceptable. The product is not auto-flammable up to 253.7°C.	Demangel B, 2015 Report 14-920010-006
Relative self-ignition temperature for solids	EU A16	BDBP12V1 Trade name: FANGA B+ BLOC P Batch: LLC 14-28-3	The self-ignition temperature of the test item was 253.7 °C	Acceptable. The product is not auto-flammable up to 253.7°C.	Demangel B, 2015 Report 14-920010-006
Dust explosion hazard			Not applicable	Not relevant	

2.2.4 Methods for detection and identification

Physico-chemical properties and Analytical method for determination of active ingredient and impurities in the technical active ingredient

Physical and chemical properties of the active substance and analytical methods for determination of active ingredients in the technical active ingredient have already been evaluated at EU level and are presented in the CAR of the active substance. The notifier TRIPLAN of the product FANGA B+ BLOC P is not the applicant that supported the annex I inclusion dossier of the active substance but it has a letter of access to these data.

Summary for Brodifacoum:

	Principle of method
Technical active substance as manufactured:	A. HPLC with UV detection at 254 nm using an internal standard B. Dissolution in methanol/dichloromethane (3:2,v/v). Determination by RP-HPLC/UV. LOQ = 0.79 µg/ml RP-HPLC/UV method for the isomeric content determination also available
Impurities in technical active substance:	A HPLC with UV detection using either an internal or an external standard, or with fluorescence detection using an external standard B. RP-HPLC/UV

Soil (principle of method and LOQ)	RP-HPLC/DAD (detection at 264 nm) – not validated A new LC-MS/MS method has been provided as post inclusion data and is validated.
Air (principle of method and LOQ)	Not relevant, since Brodifacoum is a non-volatile substance intended to be used only in solid formulations
Water (principle of method and LOQ)	Extraction from spiked samples (drinking, ground, and surface water) with dichloromethane. Extract evaporation by rotary evaporator. Residue re-dissolution in 0.5 ml of methanol for RP-HPLC/MS/MS analysis (scan in SIM and SRM mode). LOQ = 0.05 µg/l for drinking and ground water, 0.5 µg/l for surface water
Body fluids and tissues (principle of method and LOQ)	A. Extraction from spiked samples of plasma and liver with acetonitrile:ether (9:1) and acetonitrile, respectively. Evaporation to dryness by nitrogen. Residue redissolution in 2 ml of acetonitrile. Determination by RP-HPLC with fluorescence detection, using Difenacoum as internal standard. LOQ in plasma = 0.010 mg/l, LOQ in liver tissue = 0.01 mg/kg B. Blood serum: extraction from spiked samples (blood aqueous solution) with dichloromethane after centrifugation. RP-HPLC/MS/MS analysis. LOQ = 0.06 mg/l Body tissues covered under food of animal origin
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Extraction from spiked samples with ethyl acetate for cucumber, wheat, and lemon, with acetone in case of oilseed-rape. Clean-up procedure (if

	necessary) suited to the sample properties, i.e. water/fat/acid content. Determination by LC-MS/MS. LOQ = 0.01 mg/kg in all 4 matrices
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Extraction from spiked samples with dichloromethane : acetone (7:3, v/v). Purified extracts analysed by LCMS/MS. LOQ = 0.01 mg/kg

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

Report:	Ricau H, 2015
Title:	Validation of the analytical method for the determination of brodifacoum in BDBP12V1 In compliance with SANCO/3030/99 rev. 4 from 11/07/00
Document No	14-920010-009
Test facility	DEFITRACES, Z.A des Andrès, 150, Rue Pré-Magne, 69126 Brindas, FRANCE
Guidelines:	SANCO/3030/99 rev.4.
GLP	Yes

Test item

Identification: BDBP12V1 (trade name: FANGA B+ BLOC P) Batch: LLC 14-28-3

Formulation blank: BDBP12V1, batch LLC 14-28-3P

Principle

Samples are dissolved into methanol and determination is performed with HPLC-UV at 265nm using a Zorbax SB-phenyl column.

Preparation of the formulation blank

The formulation blank was previously grated. A quantity of 2.1 g (to the nearest 0.01 mg) of grated formulation blank was weighed into a 100-mL glass flask. An exact volume of 25 mL of methanol was added. The mixture was blended for 5 minutes with a laboratory blender. The solution was kept during 72 hours at room temperature then an aliquot was filtered on an ashless filter for analysis.

Preparation of the test item solution

The specimen was previously grated. A quantity of 2.1 g (to the nearest 0.01 mg) of the grated test item was weighed into a 100-mL glass flask. An exact volume of 25 mL of methanol was added. The mixture was blended for 5 minutes with a laboratory blender. The solution was kept during 72 hours at room temperature then an aliquot was filtered on an ashless filter for analysis.

Preparation of the solutions for the accuracy study

A quantity of 2.1 g (to the nearest 0.01 mg) of grated formulation blank was weighed into a 100-mL glass flask. Volumes of 0.25 mL of the REF07 solution (0.1mg/ml of brodifacoum in methanol) and 24.75 mL of methanol were added.

The mixture was blended for 5 minutes with a laboratory blender. The solution was kept during 72 hours at room temperature then an aliquot was filtered on a filter ash less for analysis (Acc 1). An identical accuracy solution was prepared with REF08 solution (0.1mg/ml of brodifacoum in methanol) (Acc 2). This fortification corresponds to approximately. 0.0012% brodifacoum/reconstituted product.

Validation of the analytical method:

Specificity	Chromatograms were provided for calibration standards, test item, blank formulation. No peak appears in the solvent blank and in the formulation blank. In the reference item and in the test item, the peaks at the retention times at about 7.095 and 7.858 min represent isomers of brodifacoum (I and II). No additional peak appears in the reference item and in the test item. Specificity is acceptable.
Linearity	The response of the detector during the analysis of brodifacoum was linear (n=5) within the range of 0.52 mg/L to 1.45 mg/L. The correlation coefficient was 0.9997. Linearity is acceptable.
Precision	Precision The precision was determined by analysing twice five specimen samplings (test item). The content of brodifacoum for each analysis was calculated with the average value of the response factor of the two calibration solutions bracketing the test item. Then, the average value of the content, the standard deviation and the Relative Standard Deviation (R.S.D.) were calculated. Mean : 0.0013% w/w RSD: 1.89% C HORWITZ: 1.3E-05 HORWITZ: 7.31% Precision is acceptable.
Accuracy	Accuracy was performed with blank formulation fortified at 0.0012% w/w with brodifacoum. Two reconstituted products were prepared. Accuracy 1: 98.1% (mean of two injections) Accuracy 2: 100.4% (mean of two injections) Results are in acceptable limits (80-120%) according to SANCO/3030/99/rev.4.

Specificity, linearity, precision and accuracy were checked and are found acceptable.

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

Brodifacoum (Doc IIA of the CAR)

The method for soil was not fully validated and a new method was requested as additional data to provide in post inclusion. A new method has been provided by the applicant of the active substance (see summary results below the following table).

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of determination	Reference
						Range	Mean	RSD		
Soil	*Brodifacoum*	RP-HPLC/DAD (detection at 264 nm)	0.016÷-0.16 mg/kg in soil, with 4 replicates per level	0.256÷-12.8 µg/ml (0.006÷-0.32 mg/kg in soil), single determinations at 8 concentrations levels. r2 = 0.9999 No matrix-matched calibration	Not highly specific LC/MS method for confirmation (only experimental conditions provided)	88.5÷-95.4 (overall)	92.9 (overall)	2.2 (overall)	LOQ = 0.016 mg/kg in soil (lowest validated concentration level)	**IIIA4.2 (a)**
Drinking water *(natural mineral water Fiuggi)*	*Brodifacoum*	RP-HPLC with MS/MS detection. Molecular ion (SIM): 521 (m/z), daughter ion (SRM): 187 (m/z) Quantification by calibration curve, except for spiking level 0.05 µg/l	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		

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of determination	Reference
						Range	Mean	RSD		
Surface water *(sampled at Desenzano, Garda lake)*		(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)			116÷-124.3 79.5÷-88.0 78.7÷-98.6 104.6÷-117	120.6 84.5 87.3 110.8	2.9 4.5 7.8 3.6		
Blood serum (*from Rabbit, lyophilized powder from clotted whole blood)*	*Brodifacoum*	RP-HPLC with MS/MS detection. Molecular ion (SIM): 523 (m/z), daughter ion (SRM): 187 (m/z) Quantification by calibration curve at 0.06 mg/l , quantification with the lowest standard calibration level at 0.3 mg/l	0.06 mg/l (n=5) 0.3 mg/l (n=6)	0.05-0.40 µg/ml (0.05-0.40 mg/l in blood serum), 4 determinations at 5 concentration levels r = 0.99679 (SIM mode) r = 0.99623 (SRM mode	Highly specific	80.8-96.6 86.2-109.1	92.1 101.7	6.5 8.6	LOQ = 0.06 mg/l (lowest validated concentration level)	**IIIA4.2 (d)(2)**
Cucumber	*Brodifacoum*	LC/MS/MS. Internal standard: Difenacoum	0.01 mg/kg (n=5) 0.1 mg/kg (n=5)	0.03-1.2 µg/ml, 2 determinations at 4	Highly specific	82-103 86-106	91 94	9 9	LOQ = 0.01 mg/kg in all 5 matrices (lowest validated	**IIIA4.3 [also IIIA4.2(d)(1) for**

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of determination	Reference
						Range	Mean	RSD		
Wheat		Linear calibration curve for all determinations, except for both spiking levels in lemon and for the validation in meat at 0.1 mg/kg (multi-level calibration standards used) Brodifacoum precursor ion 1: 521; product ion 1: 79; precursor ion 2: 523; product ion 2: 81 *Coumatetralyl* precursor ion 1: 291; product ion 1: 143; precursor ion 2: 291; product ion	0.01 mg/kg (n=5) 0.1 mg/kg (n=5)	concentration levels. Matrix-matched calibration solutions used r2: 0.9095÷-0.9963		88-126 71-90	107 84	13 9	concentration level)	**Meat only]**
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		

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of determination	Reference
						Range	Mean	RSD		
		2: 141 Product ion 1 used for measurements								

For the identification/quantification of Brodifacoum residues in soil, no fully-acceptable analytical method for Brodifacoum residues in soil was available in the relevant CAR. A new study for the determination of Brodifacoum residues in soil was presented by the Applicant post Annex I inclusion and evaluated by the IT-CA only at product authorization. The submitted LC-MS/MS method for the analysis of >Brodifacoum residues down to 0.01 mg/kg in sandy loam and soil clay meets the requirements provided for by SANCO/825/00 rev8.1and the Additional Guidance to TNsG on Data Requirements on analytical methods and supports the residue definition.
The method is highly specific (LC-MS/MS, with two mass transitions validated), linear over the range 0.005–0.250 mg Brodifacoum/kg in soil, accurate (with recovery rates at LOQ and 10xLOQ in the acceptable range 70–110%) and precise (%RSDn = 5 < 20% for each fortification level). The LOQ (as the lowest validated fortification level) complies with the relevant end-point (*Eisenia fetida* 14-d LC50 > 994 mg/kg dwt, corresponding to > 879.6 mg/kg wwt). For further details, please refer to the table below.

Summary of the analytical method for residues in soil submitted by the Applicant at product authorization

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of determination
						Range	Mean	St. dev.	
LUFA SP2.3 1510 standard soil (sandy loam)	brodifacoum (CAS 56073-10-0)	LC-MS/MS 521.1→135.1 (quantitation) 521.1→142.9 (confirmation)	0.01 mg/kg (n=5) 521.1→135.1 521.1→142.9 0.1 mg/kg (n=5) 521.1→135.1 521.1→142.9	Single determ. at 6 conc. levels over 0.005–0.250 mg/kg; 521.1→135.1: r^2 =0.9993; 521.1→142.9: r^2 =0.9999	Highly specific	79 – 90 73 – 2 82 – 94 83 – 94	85 81 88 88	5.1 9.4 4.8 5.2	0.01 mg/kg (lowest fortification level)
LUFA SP6S 3409 standard soil (clay)	brodifacoum (CAS 56073-10-0)	LC-MS/MS 521.1→135.1 (quantitation) 521.1→142.9 (confirmation	0.01 mg/kg (n=5) 521.1→135.1 521.1→142.9 0.1 mg/kg (n=5) 521.1→135.1 521.1→142.9	Single determ. at 6 conc. levels over 0.005–0.250 mg/kg; 521.1→135.1: r^2 =0.9993; 521.1→142.9: r^2 =0.9999 Matrix-matched calibration solutions used	Highly specific	71 – 79 80 – 94 74 – 77 79 – 86	74 87 75 82	4.0 6.7 1.7 3.3	0.01 mg/kg (lowest fortification level)

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MG 03: Pest Control.

Product Type 14: Rodenticide.

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

According to the uses claimed by the applicant, the product **FANGA B+ BLOC P** 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 B+ BLOC P is intended to be used in and around buildings and in open areas by professionals and non professionals users and in waste dumps / landfield area and in sewer by professional users. The products, organisms or objects to be protected are human food and animal feedstuffs and for general hygiene purposes. 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 0):

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

Mice: 30-40 g bloc/secured bait point separated by 1-2 m.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The applicant submitted the following studies:

- Study n°: 14TOX044: laboratory study:

For house mice (*Mus musculus*), the mean palatability percentage of the 3 months aged FANGA B+ BLOC P is 63 % and the mortality percentage of 100%.

- Study n°: 15TOX002: laboratory study:

For brown rats (*Rattus norvegicus*), the mean palatability percentage of the 6 months aged FANGA B+ BLOC P is 43 % and the mortality percentage of 100%.

- Study n°: 2013 BCD SAG16: laboratory study:

For brown rats (*Rattus norvegicus*), A 2 years old bait has been aged in damp condition (T°: 30-35 °C; RH: 80 %), the mean palatability percentage 20 % and the mortality percentage of 100%.

- Study n°: 14TOX043: laboratory study:

For black rats (*Rattus rattus*), the mean palatability percentage of the 6 months age FANGA B+ BLOC P is 40 % and the mortality percentage of 100%.

- Study n°2017.BCD.SAG14: field study

The study has been performed in an infested agricultural building with brown rats (*Rattus norvegicus*). The quantity of bait (FANGA B+ BLOC P, 5 months aged) applied by bait point was 200 g.

The assessed bait has been very well accepted and the efficacy is estimated at 100 %.

- Study n°2018.BCD.SAG14: field study

The study has been performed in an infested agricultural building with black rats (*Rattus rattus*). The quantity of bait (FANGA B+ BLOC P, 5 months aged) applied by bait point was 200 g.

The assessed bait has been very well accepted and the efficacy is estimated at 100 %.

- Study n°2016.BCDSAG14: field study

The study has been performed in an infested agricultural building with house mice (*Mus musculus*). The quantity of bait (FANGA B+ BLOC P, 5 months aged) applied by bait point was 100 g.

The assessed bait has been very well accepted and the efficacy is estimated at 100 %.

- Study n°2019.BCDSAG16: field study

The study has been performed in an infested agricultural building with house mice (*Mus musculus*). The quantity of bait (FANGA B+ BLOC P, 21 months aged) applied by bait point was 40 g.

The assessed bait has been very well accepted and the efficacy is estimated at 100 %.

French competent authorities (FR CA) consider that the elements presented in the dossier demonstrate the efficacy of the product against mice (*Mus musculus*), black rats (*Rattus rattus*) and brown rats (*Rattus norvegicus*) for use in and around buildings, open areas and waste dumps / landfills and in sewer.

The applicant claims a maximum storage duration of 4 years. But the product does not contain preservative and the efficacy tests have been performed with the product aged of 2 years maximum). Then the efficacy is not demonstrated for products aged of more than 2 years.

Furthermore, no test with a product older than 5 months has been submitted for *Rattus rattus*. A maximum duration of storage of 2 years is proposed. A new field efficacy will have to be provided in support of the authorisation, within one year after authorisation to confirm the efficacy of the 2 years product on this species.

All efficacy studies are presented in annex 7.

2.2.5.4 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 1 to 9 days after ingestion.

Conclusion on the efficacy of the product

Conclusions of efficacy and risk assessment

French competent authorities (FR CA) assessed that the product FANGA B+ BLOC P has shown a sufficient efficacy for the control of *Rattus norvegicus, Rattus rattus* and *Mus musculus* in and around building, in open areas, in waste dumps, landfills and in sewers (only *Rattus norvegicus*) but only on the highest application rates claimed (40 per baiting point for house mice and 200 g per baiting point for rats. Indeed, the efficacy tests presented in the dossier were performed at 40 g per baiting point for house mice and 200 g per baiting point for rats (*Rattus rattus* and *Rattus norvegicus*)

The applicant claims a maximum storage duration of 4 years. But the product does not contain preservative and the efficacy tests have been performed with the product aged of 2 years maximum. Then the efficacy is not demonstrated for products aged of more than 2 years.

Furthermore, no test with a product older than 5 months has been submitted for *Rattus rattus*. A

maximum duration of storage of 2 years is proposed. A new field efficacy will have to be provided in support of the authorisation, within two years after authorisation to confirm the efficacy of the 2 years product on this species.

The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management every two years.

2.2.5.5 Occurrence of resistance and resistance management

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%. 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[11]; Lund, 1984[12]; Pelz et al. 1995[13]). 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[14]). 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[15]).

Recent 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 (*Rattus norvegicus*) populations to coumafene. Moreover, a recent 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 bromadionone (Grandemange *et al*., 2009). More recently, 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. So, resistance to second generation anticoagulant rodenticides should not be minimized.

Only 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*").

Resistance management strategies

The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance.

CropLife International has published a strategy for resistant management of rodenticides (RRAC 2003). The habitat management is addressed in the strategy in addition to chemical control. The access of rodents should be restricted by physical barriers and no food should be available for rodents. Rotation between different anticoagulants is not a reliable means of managing the anticoagulant resistance, as all anticoagulants have the same mode of action and the nature of resistance is also similar. The resistant individuals can be identified by conducting a blood clotting response (BCR) test (Gill et al. 1993, RRAC 2003). The problem with the BCR test is that it has proven difficult to standardize and it produces both false positives and negatives (Pelz et al.

[11] Greaves J. H.; Shepherd D. S.; Gill, J. E. (1982): An investigation of difenacoum resistance in Norway rat populations in Hampshire. *Annals of Applied Biology* 100, 581–587.

[12] LUND, M. (1984): Resistance to the second generation anticoagulant rodenticides. *In Proceedings of 11th vertebrate pest conference*, Sacramento, Ca. March 6-8, 1984: 89-94.

[13] Pelz H-J, Ha¨nisch D, Lauenstein G (1995) Resistance to anticoagulant rodenticides in Germany and future strategies to control *Rattus norvegicus. Pestic Sci* 43, 61–67

[14] Greaves J. H.; Cullen-Ayres P. B. (1988): Genetics of difenacoum resistance in the rat. In: J. W. Suttie (Ed.), Current advances in vitamin K research, Elsevier, N.Y., 381–388.

[15] Quy R.J., Shepherd D.S., Inglis I.R. (1992): Bait avoidance and effectiveness of anticoagulant rodenticides against warfarin- and difenacoum-resistant populations of Norway rats (Rattus norvegicus). *Crop Protection*, Volume 11, Issue 1, February 1992, Pages 14-20

2005). In order to follow the occurrence and spread of difenacoum resistance, wild rats should be continuously monitored for resistance in the rodent controlled area.

The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management every two years.

2.2.5.6 Evaluation of the label claims

French competent authorities (FR CA) assessed that the product FANGA B+ BLOC P has shown a sufficient efficacy for the control of *Rattus norvegicus, Rattus rattus* and *Mus musculus*.

The application rates validated are the following:

Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g bloc/secured bait point separated by 5-10 m.

Brown rats in sewers (*rattus norvegicus):* 200 g bloc/ secured bait point separated by 5-10 m.

House mice (*Mus musculus*): 40 g bloc/secured bait point separated by 1-2 meters.

Bait points should be controlled and resupplied as long as the bait is consumed:

- 3 days after the first application then weekly for use in and around buildings and open areas;
- 1 week after the first application then monthly for use in waste dumps, landfills and in sewers.

The product FANGA B+ BLOC P is supplied in sachets of different amounts. The applicant has to adapt the sachets sizes to the efficient doses. The amount of bait per bait station or bait points must not exceed the recommended application rates.

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

The product FANGA B+ BLOC P is intended to be used for the control of rats (*Rattus rattus* and *Rattus norvegicus*) and mice (*Mus musculus*) in and around buildings, and in open areas by professional and non-professional users; in waste dumps and in sewers (only on *Rattus norvegicus*) by professional users.

Rats (*Rattus norvegicus* and *Rattus rattus*): 180-200 g bloc/secured bait point separated by 5-10 m.

Brown rats in sewers (*rattus norvegicus):* 200 g bloc/ secured bait point separated by 5-10 m.

Mice (*Mus musculus*): 30-40 g bloc/secured bait point separated by 1-2 m.

The product is a ready-to-use block bait with no dilution nor other substances added for application. The mode of application claimed by the applicant is a manual application by professional users in secured bait point (bait stations).

2.2.6 Risk assessment for human health

2.2.6.1 Hazard potential

2.2.6.1.1 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** AR.
Brodifacoum (CAS no. 56073-10-0) was notified as an existing active substance, by Syngenta Limited and Activa / Pelgar Brodifacoum and Difenacoum Task Force, hereafter referred to as the 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.

A (data from Syngenta) and B (data from Activa/PelGar)

- **Toxicokinetics**

A:

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 (≅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 ≅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 ±6.25%) in the washing fluid. **A 'surrogate value' 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.

B:

Read across to data from some related 2nd 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 2nd 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 2nd generation anticoagulant *Difenacoum*, a 3% dermal absorption value was adopted for the exposure calculation (below reported under Section 2.2.1.8). 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 2nd 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**

A:

Brodifacoum was very toxic to rats and mice with similar oral LD_{50} 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.

B:

Brodifacoum is very toxic if swallow (oral LD_{50} <5 mg/kg bw) or in contact with skin (dermal LD_{50}= 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.* 2nd 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**

A:

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.

B:

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**

A:
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 was observed at the highest doses. The applicants 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.

B:
Brodifacoum was tested for genotoxic activity in the bacterial reverse mutation test in *Salmonella thyphimurium* in strains TA 98, TA 100, TA 102, TA 1535 and TA 1537, up to 5000 □g/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**

A, B:

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

- **Reproductive and developmental toxicity**

A:

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*.

B:

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 need 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 developmentakl 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**

A:

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

B:

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 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 the 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 harmonised classification of the active substance is the following:

Classification under regulation (EC) 1272/2008
Acute Tox 1 H310 Acute Tox 2 H300 STOT RE Cat 1 H372 No specific limit concentrations

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

A: The Acceptable Exposure Level for acute exposure (AEL_{acute}) 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_{acute} results to be of 3.3×10^{-6} mg/kg/day.

The Acceptable Exposure Level for repeated exposure (AEL_{chr}) 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_{chr} results to be of 3.3×10^{-6} mg/kg/day.

B: The Acceptable Exposure Level for acute exposure (AEL_{acute}) 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_{acute} results to be of 6.7×10^{-6} mg/kg bw/d.

The Acceptable Exposure Level for repeated exposure (AEL_{chr}) 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_{chr} results to be of 3.3×10^{-6} mg/kg bw/day.

TMIII09 agreed to derive $AEL_{medium\ term}$ consistently with what decided for the other AVK rodenticides. Therefore, $AEL_{medium\ term}$ 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 $AEL_{medium\ term}$ results to be of 6.7×10^{-6} mg/kg bw/day.

Conclusions:

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

- $AEL_{acute\ and\ medium\ term}$ of 6.7×10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day;
- AEL_{chr} of 3.3×10^{-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.

2.2.6.1.2 Toxicology of the substance(s) of concern

The biocidal product contains no substances of concern.

2.2.6.1.3 Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements.
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 realized with the product FANGA BLOC SP PRO, a block formulation containing 0.005% of brodifacoum. The compositions of FANGA BLOC SP PRO and FANGA B+ BLOC P are considered similar.

2.2.6.1.3.1 PERCUTANEOUS ABSORPTION

A default value of 0.047% was considered for product containing 0.005% of brodifacoum, as mentioned in the brodifacoum assessment report.
This value has been considered relevant for the product FANGA B+ BLOC P containing 0.0012% of brodifacoum. Indeed, no major increase in the dermal absoprtion value is expected with such very low concentrations of active substance in products and considering that the concentrations are in the same order of magnitude.

2.2.6.1.3.2 ACUTE TOXICITY

Oral route

Route	Method	Species	Dose level	LD50	Study reference
Oral	OECD 423	Rat 3 males and 3 females	2000mg/kg bw	>2000 mg/kg bw	Colas S. (2012), GLP study

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_{50} of the test item is higher than 2000 mg/kg/bw.

Dermal route

Route	Method	Species	Dose level	LD50	Study reference
Dermal	OCDE 402	Rat 5 males and 5 females	2000 mg/kg bw	>2000 mg/kg bw	Colas S. (2012), GLP study

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_{50} of the test item is higher than 2000 mg/kg/bw.

Based on the above-mentioned results, no classification is required for FANGA B+ BLOC P.

2.2.6.1.3.3 IRRITATION AND CORROSIVITY

Route	Method	Species	Dose level		Study reference
skin	OECD 404	Rabbit NZ 3 females	0.5 g	No irritant	Colas S. (2012), GLP study
eye	OCDE 405	Rabbit NZ 3 females	0.1 g	No irritant	Colas S. (2012), GLP study

Based on the results of the irritation assays on rabbit's skin and eye, no classification is required for FANGA B+ BLOC P.

2.2.6.1.3.4 SENSITISATION

Route	Method	Species	Dose level		Study reference
skin	OECD 429	Mice16 (12 for the treated groups)	Topical way of induction: 5, 10, 25% of the test item	No skin sensitizing	Colas S. (2012), GLP study

Based on the results of the LLNA, no classification is required for FANGA B+ BLOC P.

2.2.6.1.3.5 OTHER STUDIES

No other studies are performed on FANGA B+ BLOC P.

2.2.6.2 Human exposure assessment

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

Exposure path	**Industrial use**	**Professional use**	**General public**	***via* the environment**
Inhalation	Not relevant	Potentially significant	Negligible	Negligible
Dermal	Not relevant	Potentially significant	Potentially significant	Negligible
Oral	Not relevant	Negligible	Potentially significant	Negligible

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

2.2.6.2.2.1 EXPOSURE OF PROFESSIONAL USERS

FANGA B+ BLOC P is used for the control of rats and mice for use indoor and outdoor, with the purpose of protecting human food and animal feedstuffs, and for human hygiene.
The product is supplied in bulk and sachets (PE or PP). Considering the nature of sachet, a dermal exposure during cleaning is taken into account. Exposure assessment has been realized with the dose of 200 g of product for the control of rats. This assessment covers the assessment for mice as the intended doses are lower.

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 loading** of 5 wax blocks of 20g per one manipulation was 27.79 mg. The following parameters were taken into account:

- active substance in product: 0.0012 %,(w/w);
- number of blocks per bait site[16]: 50 for control of rats
- dermal absorption: 0.047 %,
- body weight: 60 kg.

Thus, the systemic dose of brodifacoum per placing of one bait site is 2.61×10^{-8} mg/kg bw/event for control of rats and mice (because the amount of disposed bait is not taken into account).

The harmonized number of manipulations for rodenticides anticoagulant set in the HEEG opinion agreed at TM III 2010 was used to assess the overall exposure systemic dose. Considering 60 loading are done per day, the systemic dose via skin is 1.57×10^{-6} mg a.s/kg bw/day for the control of rats.

[16] Although the block weights 4 g and not 20 g as in the CEFIC study, it was considered that the important parameter is the number of blocks loaded rather than the weight of the block

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** of one bait site is 5.70 mg. The following parameters were taken into account:

- active substance in product: 0.0012 %,(w/w);
- dermal absorption: 0.047 %,
- body weight: 60 kg.

Thus, the systemic dose of brodifacoum per cleaning of one bait site is 5.36 x 10^{-10} mg/kg bw/event for control of rats and mice (because the amount of disposed bait is not taken into account).

The harmonized number of manipulations for rodenticides anticoagulant set in the HEEG opinion agreed at TM III 2010 was used to assess the overall exposure systemic dose. Considering 15 cleaning are done per day, the systemic dose via skin is 8.04 x 10^{-9} mg a.s/kg bw/day for the control of 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 1.58 x 10^{-6} mg/kg bw/day without PPE for the control of rats and mice.

2.2.6.2.2.2 EXPOSURE OF NON-PROFESSIONAL USERS

The product is only supplied in sachets for non professionnal users. Considering the nature of sachet (PE or PP), a dermal exposure during cleaning is taken into account. Exposure assessment has been realized with the dose of 200 g of product for the control of rats. This assessment covers the assessment for mice as the intended doses are lower.

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** of one bait site is 5.70 mg. The following parameters were taken into account:

- active substance in product: 0.0012 %,(w/w);
- dermal absorption: 0.047 %,
- body weight: 60 kg.

Thus, the systemic dose of brodifacoum per cleaning of one bait site is 5.36 x 10^{-10} mg/kg bw/event for control of rats and mice (because the amount of disposed bait is not taken into account).

The harmonized number of manipulations for rodenticides anticoagulant set in the HEEG opinion agreed at TM III 2010 was used to assess the overall exposure systemic dose. Considering 5 cleaning are done per day, the systemic dose via skin is 2.68 x 10^{-9} mg a.s/kg bw/day for the control of 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 2.68 x 10^{-9} mg/kg bw/day without PPE for the control of rats and mice.

2.2.6.2.2.3 INDIRECT EXPOSURE AS A RESULT OF USE OF THE ACTIVE SUBSTANCE IN BIOCIDAL PRODUCT

Exposure can occur during handling of dead rodents by professionnal and general public.
However, this scenario is excluded and considered of low relevance due to unrealistic assumptions (TNsG on human exposure (2007)).
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 6.7 x 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 7.4 mg of product per day by an infant is needed to exceed the AEL.

2.2.6.3 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 ($3.3x10^{-6}$ mg/kg bw/day for long-term exposure and $6.7\ x10^{-6}$ mg/kg bw/day for short-medium term exposure).

2.2.6.3.1 Risk for direct exposure

2.2.6.3.1.1 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 B+ BLOC P, even if gloves are not worn (%AEL at 48%) for the control of rats and, by extension, of 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 2.7.3-1: Summary of risk characterisation for professionals for the control of rats

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Bulk formulation (exposure during loading and cleaning phases)				
Professionnal (without gloves)	3.3×10^{-6}	1.58×10^{-6}	48%	Acceptable

2.2.6.3.1.2 NON-PROFESSIONAL USERS

Based on the risk assessment of the active substance, the risk for non-professional users resulting from the intended use is acceptable for FANGA B+ BLOC P (%AEL at 0.04%) for the control of rats and, by extension, of mice.

Table 2.7.3-1: Summary of risk characterisation for non professionals for the control of rats

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Sachet formulation (PE or PP) (exposure during the cleaning phase)				
Non Professionnal	6.7×10^{-6}	2.68×10^{-9}	0.04%	Acceptable

2.2.6.3.2 Risk for indirect exposure

Based on a reverse scenario, more than 7.4 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 B+ BLOC P 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.

2.2.6.3.3 Summary of risks characterisation of the product for human health

Based on the risk assessment of the active substance, the risk for professional and non-professional users resulting from the intended use is acceptable for FANGA B+ BLOC P for the control of rats and mice.

Risk of secondary poisoning to infants and children is considered as relevant. Therefore, even if FANGA B+ BLOC P contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children.

2.2.6.3.4 Exposure to residues in food

In Annex 6 “Residue behaviour”, the results of the residue assessment are laid out.

The biocidal product will not come into contact with food and it is not applied by spraying or dusting such that food or feeding stuffs could be contaminated. Therefore there is no requirement to assess potential residues on foodstuffs. 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.

2.2.6.4 Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

2.2.7 Risk assessment for the environment

As the product contains no substance of concern except brodifacoum, it is considered that risks posed to environment following the use of FANGA B+ BLOC P 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 B+ BLOC P is a rodenticide in wax block bait form (packaged in sachet or bulk) containing 0.0012% brodifacoum (0.01 g/kg). The product is in the form of a block (individually packaged in sachet). Baits are placed in secured bait box for professional and non-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 B+ BLOC P 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);
- Sewer (professional use only)

For the intended uses, the terrestrial (including groundwater) compartment and the aquatic compartment are the relevant compartments of release. The risks are also calculated for primary and secondary poisoning.
The physico-chemical input parameters which were used are as follows:

PHYSICO-CHEMICAL PROPERTIES	**Value**	**Unit**
Molecular weight	523.4	[g.mol-1]
Vapour pressure at test temperature	<< 1 x 10^{-6}	[Pa]
Temperature at which vapour pressure was measured	20	[°C]
Octanol-water partition coefficient	6.12	[log10]
Organic carbon-water partition coefficient	9155	[L.kg-1]
Half-life in soil	Not biodegradable*	[d]
BCF fish	35645	L.kg-1
Solubility in water	0.058	mg/L^{-1}, PH7, 20°C

*according to EUSES, the default DT_{50} value for soil to be used for risk assessment is 1.0E+06 d when the substance is not biodegradable

2.2.7.1 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 Assessment Report (AR) of brodifacoum owned by Syngenta Limited and Activa / Pelgar Brodifacoum and Difenacoum Task Force[17].

2.2.7.1.1 Degradation

2.2.7.1.1.1 ABIOTIC DEGRADATION

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.

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.

Photolysis in soil

No data on photolysis of the active substance in soil has been submitted in the combined AR of brodifacoum.

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 Guidance of BPR Vol. IV Part B IV Part B[18], the half-live has been recalculated considering $C_{OH} = 0.5 * 10^6$ molec/cm^3; corresponding to a DT_{50} of 0.217 days). There are no predicted effects on the atmosphere.

2.2.7.1.1.2 BIOTIC DEGRADATION

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 degradation of the active substance in water/sediment system has been submitted in the combined AR of brodifacoum.

Degradation in STP

No study on degradation of the active substance in sewage treatment plant system has been submitted in the combined AR of brodifacoum.

Terrestrial compartment

Brodifacoum is persistent in soil with a DT_{50} value of 157 days at 20°C, corresponding to a DT_{50} value of 298 days at 12°C.

[17] Syngeta 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, Revision: 16 december 2010

[18] : Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment (active substances), Version 1.0, April 2015

2.2.7.1.2 Distribution

Based on literature data, the Koc value (50 000 L/kg) 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 shows 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.

2.2.7.1.3 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 (according to Equation 75; Guidance of BPR Vol. IV Part B IV Part B).

The terrestrial BCF has been estimated with calculation method:

$BCF_{earthworm}$ = 15 820 L/kg (according to Equation 82d; Guidance of BPR Vol. IV Part B IV Part B).

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

2.2.7.1.4 Behaviour in air

The vapour pressure of brodifacoum has been determined to be << 1 x 10^{-6} Pa (OECD 104, EC methods A.4). Furthermore, Henry's law constant has been calculated to be << 2.18 x 10^{-3} $Pa.m^3.mol^{-1}$ 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).

2.2.7.2 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[19].

2.2.7.2.1 Aquatic compartment (including water, sediment and STP)

2.2.7.2.1.1 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 toxic to aquatic organisms at low concentrations. No long-term tests have been performed. Studies are available for the three trophic levels (fish, daphnia and algae). *Selenastrum capricornutum* is the most sensitive species with a 72h E_rC_{50} of 0.04 mg a.s./L.

Table 1: Toxicity to freshwater aquatic organisms (measured concentrations)

[19] Syngeta 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, Revision: 16 december 2010

Guideline / Test method	Species	Endpoint	Results (mg a.s./L)	Reference
OECD 203	*Oncorhynchus mykiss* - fish	LC_{50} – 96h	0.042	Activa / PelGar Brodifacoum and Difenacoum Task Force CAR a.s. Doc III-A 7.4.1.1
OECD 202	*Daphnia magna* - invertebrate	EC_{50} – 48h	0.25	Activa / PelGar Brodifacoum and Difenacoum Task Force CAR a.s. Doc III-A 7.4.1.2
OECD 201	*Selenastrum capricornutum* - algae	E_bC_{50} – 72h E_rC_{50} – 72h	0.016 0.04	Activa / PelGar Brodifacoum and Difenacoum Task Force CAR a.s. Doc III-A 7.4.1.3

Justification of $PNEC_{water}$

According to the Guidance of BPR Vol. IV Part B, the $PNEC_{water}$ is derived from the 72h E_rC_{50} value (0.04 mg a.s./L) for *Selenastrum capricornutum* divided by an assessment factor of 1000.

PNECwater = 0.04 µg a.s./L.

2.2.7.2.1.2 SEDIMENT DWELLING ORGANISMS

No experimental data are available for sediment dwelling organisms. A $PNEC_{sediment}$ (0.043 mg/kg_{wwt}) is derived through the Equilibrium Partitioning Method. However, due to the absence of measured data for the determination of a $PEC_{sediment}$ and according to the Guidance of BPR Vol. IV Part B 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 Guidance of BPR Vol. IV Part B and considering the log Kow > 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.

2.2.7.2.1.3 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 effect of brodifacoum on aerobic biological sewage treatment processes was expected. Due to the lack of measured values of test substance concentration, the EC_{10} was conservatively set greater than brodifacoum water solubility (0.058 mg a.s/L).

Table 2: Toxicity to STP microorganisms

Guideline/Test method	Species / Inoculums	Endpoint / Type of test	Duration	Results [mg a.s/L]				Reference
				EC_{10}	EC_{20}	EC_{50}	EC_{80}	
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 $PNEC_{micoorganisms}$
According to Guidance of BPR Vol. IV Part B when an EC_{10} from a respiration inhibition test is used, an assessment factor of 10 must be applied and a PNEC STP microorganisms > 0.0058 mg a.s/L can be derived.

Additional endpoints:
According to the combined AR of brodifacoum, a lower PNEC value for sewage treatment microorganisms is provided by Syngeta Limited:

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 must be used in the risk assessment.

2.2.7.2.2 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.

2.2.7.2.3 Terrestrial compartment

No effect of brodifacoum, in soil concentration ranging up to 994 mg/kg dry weight, were found on earthworms in a test conducted according to the guideline OECD 207. LC_{50} was determined to be > 994 mg/kg dry weight, corresponding to a LC_{50} >879.6 mg/kg in wet weight.

Table 3: Toxicity to soil organisms

Guideline / Test method	Species	Endpoint / Type of test	Exposure		Results (mg a.s/kg wwt soil)		Reference
			design	duration	NOEC	LC_{50}	
OECD 207	*Eisenia foetida*	LC_{50}	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 $PNEC_{soil}$

Since LC_{50} was determined to be >879 mg/kg wet weight, when corrected for soil humidity, an assessment factor of 1000 was used in accordance with Guidance of BPR Vol. IV Part B.

$PNEC_{soil}$ > 0.88 mg/kg wet weight

2.2.7.2.4 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 4: Toxicity to birds and mammals (key studies)

Guideline / Test method	Species	Endpoint / Type of test / Duration	Results NOEC/NO(A)EL	Results LD_{50}	Reference
OPPTS 850.2100	Japanese quail	LD_{50}/ acute oral Single dose followed by 14 days oservation	-	LD_{50} = 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 diathesies 2-generation	NO(A)EL Parental (females) = 0.001 mg/kg bw/day)	-	Morris, 1995

2.2.7.2.4.1 PRIMARY POISONING & 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: a LD_{50} value =< 5 mg a.s. /kg bw is provided.

Additional endpoints:
According to the combined AR of brodifacoum, a lower **LD_{50}** value of **0.4 mg a.s. /kg bw** (recalculated into **LC_{50} = 8 mg/kg food**, using the conversion factor bw/dfi of 20 from table 22 in the Guidance of BPR Vol. IV Part B is the lowest value for the acute toxicity) 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).

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

Additional endpoints:
According to the combined AR of brodifacoum, a lower LD50 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 LD50 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).

Studies on dietary toxicity were submitted by another applicant in the combined AR and provided a **LC_{50} = 0.72 mg/kg food**. 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 mg/kg bw/day was estimated. According to the Guidance of BPR Vol. IV Part B, the NOAEL is transformed into a NOEC using a conversion factor of 20, and the AF_{oral} of 90 is applied to this NOEC, which results in a

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

equivalent to

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

For **birds,** the NOEC for brodifacoum is based on the results of the chronic toxicity study with difenacoum (on 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 mg/kg, male and females) and brodifacoum (LD_{50} = 19 mg/kg bw), both related to Japanese quail. Brodifacoum results show high toxicity 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 Guidance of BPR Vol. IV Part B, an assessment factor of 30 is applied to derive the PNEC:

$PNEC_{oral}$ for birds (dose) = 0.0012/30 = 4E-05 mg/ kg bw/ day
equivalent to
$PNEC_{oral}$ for birds (conc. In food) = 0.012/30 = 43E-04 mg/kg food

Additional endpoints: according to the combined AR of brodifacoum, a lower **$PNEC_{oral}$ 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. A NOEC = 0.0038 mg brodifacoum /kg diet and a NOEL = 3.85E-04 mg Brodifacoum/kg bw/d are derived.
According to Guidance of BPR Vol. IV Part B, an assessment factor of 30 is applied to derive the PNEC:

$PNEC_{oral}$ for birds (dose) = 1.3E-05 mg/ kg bw/ day
equivalent to
$PNEC_{oral}$ for birds (conc. In food) = 1.3E-04 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.

2.2.7.2.5 Summary of PNECs of the active substance Brodifacoum

Table 5: Summary of the brodifacoum (a.s.) PNECs used for risk assessment

Compartment		Test Value	AF	PNEC	Source
Aquatic	PNECwater	72h E_rC_{50} = 0.04 mg a.s./L	1000	0.04 µg a.s./L	Combined AR
	$PNEC_{STP}$	EC_{10} > 0.0038 mg a.s. /L	100	> 0.0038 mg a.s/L	combined AR
Terrestrial	$PNEC_{soil}$	14-d LC_{50} > 879.6 mg a.s. /kg ww soil	1000	> 0.88 mg/kg wet weight	Combined AR
Primary and secondary poisoning	$PNEC_{oral\ for\ birds}$	NOEC = 0.0038 mg/kg food NOEL = 3.85E-04 mg/kg bw/day	30	1.30E-04 mg/kg food 1.30E-05 mg/ kg bw/ day	Combined AR
	$PNEC_{oral\ for\ mammals}$	NO(A)EL=0.001mg a.s/kg bw/day NOEC= (0.001*20)=0.02 mg a.s/kg food	90	1.10E-05 mg/kg bw/day 2.22E-04 mg/kg food	Combined AR

According to the combined AR, the lowest PNEC values (from Syngenta limited or Activa / PelGar Brodifacoum and Difenacoum Task Force) are used in the risk assessment.

2.2.7.2.6 PBT and ED Assessment

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

Bioaccumulation
Based on log Kow = 6.12 and BCFfish = 35 645 $L.Kg^{-1}$ (according to Equation 75; Guidance of BPR Vol. IV Part B), brodifacoum potentially fulfils the B criterion and vB criterion.

Toxicity
Brodifacoum is proposed to be classified as Repr. Cat 1 or 2, R61. Brodifacoum is also proposed to be classified as T+;R26/27/28, R43, R48/23/24/25, R61, N;R50/53. According to the Guidance of BPR Vol. IV Part B, brodifacoum fulfils the T criterion.

Brodifacoum is considered as a potential PBT, according to the Guidance of BPR Vol. IV Part B.

2.2.7.3 Effects on environmental organisms for biocidal product

It is important to note that the applicant did not provide ecotoxicological data about the biocidal product FANGA B+ Bloc P. So the whole effect assessment for the product 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 B+ BLOC P, 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.

2.2.7.3.1 Aquatic organisms

Refers to section 2.2.7.2.1

2.2.7.3.2 Sediment dwelling organisms

Refers to section 2.2.7.2.1

2.2.7.3.3 STP micro-organisms

Refers to section 2.2.7.2.1

2.2.7.3.4 Atmosphere

Refers to section 2.2.7.2.1

2.2.7.3.5 Terrestrial compartment

Refers to section 2.2.7.2.1

2.2.7.3.6 Non compartment specific effect relevant to the food chain

Refers to section 2.2.7.2.1

2.2.7.3.7 Summary of PNECs

Refers to section 2.2.7.2.1

2.2.7.4 Environmental exposure assessment

As the product contains no substance of concern except brodifacoum, it is considered that risks posed to environment following the use of FANGA B+ BLOC P 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 B+ BLOC P is a rodenticide in wax block bait form (packaged in sachet or bulk) containing 0.001% brodifacoum[20] (0.01 g/kg). –The product is in the form of a block (individually packaged in sachet). Baits are placed in secured bait box for professional and non-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.

[20] Please note that a round value for the brodifacoum percentage has been used for the ERA. The validated concentration, for technical substance is 0.001209%. The PEC/PNEC ratios are slightly impacted by this approximation but the conclusions are not changed.

FANGA B+ BLOC P 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);
- Sewer (professional use only)

For the intended uses, the terrestrial (including groundwater) compartment and the aquatic compartment are the relevant compartments of release. The risks are also calculated for primary and secondary poisoning.
The physico-chemical input parameters which were used are as follows:

PHYSICO-CHEMICAL PROPERTIES	**Value**	**Unit**
Molecular weight	523.4	[g.mol-1]
Vapour pressure at test temperature	<< 1 x 10^{-6}	[Pa]
Temperature at which vapour pressure was measured	20	[°C]
Octanol-water partition coefficient	6.12	[log10]
Organic carbon-water partition coefficient	9155	[L.kg-1]
Half-life in soil	Not biodegradable*	[d]
BCF fish	35645	L.kg-1
Solubility in water	0.058	mg/L^{-1}, PH7, 20°C

*according to EUSES, the default DT_{50} value for soil to be used for risk assessment is 1.0E+06 d when the substance is not biodegradable

2.2.7.4.1 Aquatic compartment (surface water, sediment, STP)

2.2.7.4.1.1 SEWER

Exposure of the aquatic compartment *via* the STP after the treatment with rodenticides is only relevant for sewers. If unused product, urine or excreta from target rodents or dead rodents enter the sewage system, brodifacoum may reach surface waters via the final effluent discharged from a sewage treatment plant (STP). Estimates of brodifacoum concentrations in surface water that arise from this application are calculated below.

ESD PT14 considers a typical scenario that involves a sewerage network serving a population equivalent (PE) of 10 000 and fitted with 300 access manholes. A maximum of 300 g bait is initially deployed beneath each manhole, giving a total of 90 kg formulated product distributed throughout the sewer network. The ESD PT14 scenario is a worst case because the applicant required a dose of 200 g bait/manhole. Maximum input of rodenticide into sewage water occurs during the first week of pulse baiting campaigns and EUBEES 2 indicates a figure of one third of the total deployment (i.e. 30 kg formulated product) in the first seven days. According to the ESD PT14, the default amount of product used in the control operation in sewer is 30 kg during the first 7 days of the control operation. This value is used in the following risk assessment for the use of FANGA B+ BLOC P in sewer.

In the worst case approach (default values), no metabolisation of the active substance is considered ($F_{released}$ = 0.9).

Elimination processes in STP are calculated using the K_{oc}, the physico- chemical parameters and the results of biodegradation tests according to SimpleTreat. Due to the low vapour pressure and Henry's law constant and because difenacoum is not readily biodegradable, only relevant elimination process is partitioning to organic matters. EUSES calculations predict that 48.6 % is directed to water, 51.1 % to sludge and 0.3 % to air.

Table 6: Input values, emission and concentration in sewage water calculated according to the EUBEES 2 scenario for sewer system and the Guidance of BPR Vol. IV Part B - Worst case scenario with the default values and typical case scenario.

Symbol	Variable/parameters	Default values	Unit
Qprod:	Amount of product used	30	[kg.camp-1]
Fcproduct:	Fraction of active substance in product	0.01	[gai.kg -1]
Temission	Number of emission days (realistic worst case during the control operation)	7	[d-1]
Freleased	Fraction released	0.9	[-]
Fmetabolised:	Fraction of active ingredient metabolised	0	[-]
F STP water	Fraction of emission directed to water by STP	0.486	[-]
F STP sludge	Fraction of emission directed to sludge by STP	0.511	[-]
Elocal STP	Local emission rate to the STP	3.86E-05	[kg.d-1]
Clocalinf	Concentration in untreated wastewater	1.93E-05	[mg.kg -1]
Ceff = PEC stp (eq.33)	Concentration in the STP effluent	9.37E-06	[mg.L-1]
Clocal water **(eq.45)**	**Local concentration in surface water**	**9.25E-07**	**[mg.L-1]**
Clocalsed (eq.50)	Local concentration in sediment	1.85E-04	[mg.kg-1]

2.2.7.4.1.2 OTHER USES

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.

2.2.7.4.2 Atmospheric compartment

Due to its physico-chemical properties (low vapour pressure of 2.6 x 10^{-22} Pa at 20°C and low Henry's law constant of 2.35 x 10^{-18} $Pa.m^3.mol^{-1}$), 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 B+ BLOC P biocidal product.

2.2.7.4.3 Terrestrial compartment (soil and groundwater)

2.2.7.4.3.1 IN AND AROUND BUILDINGS

The exposure assessment has been carried out according to the ESD (Larsen, 2003) for rodenticides (ESD PT14)[21] and the Guidance of BPR Vol. IV Part B. The ESD 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:

[21] EUBEES 2 - Emission scenario document for biocides used as rodenticides (Larsen, 2003)

- A brodifacoum concentration of 0.001% (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).

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 blocks 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.

In both scenarios, the direct and disperse brodifacoum releases ($Elocal_{soil}$, mg) 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 Guidance of BPR Vol. IV Part B equations. The degradation in soil was not considered in the calculations.

Table 7: PEC brodifacoum in soil and groundwater for uses in and around buildings

		Refined and specific parameters: typical scenario		
Symbol	**Variable/parameters**	**Rat**	**Mouse**	**Unit**
INPUTS				
$Q_{prod:}$	Amount of product used in control operation for each bait box	200	40	[g]
$Fc_{product}$:	Concentration of active substance in product	0.01	0.01	[$g.kg^{-1}$]
Nsites:	Number of application sites	10	10	[-]
N_{refil}:	Number of refilling times	5	5	[-]
$F_{release\text{-}D,\ soil}$:	Fraction of product released directly to soil	0.01	0.01	[-]
$F_{release\text{-}ID,\ soil}$:	Fraction released indirectly to soil	0.9	0.9	[-]
K_{oc}	Organic carbon adsorption coefficient	9 155	9 155	[L.kg-1]
Distance	Distance between 2 bait points	5	1	[m]
$AREA_{exposed\text{-}D}$:	Area directly exposed to rodenticide originating from one bait box	0.09	0.09	[m^2]
$AREA_{exposed\text{-}ID}$:	Area indirectly exposed to rodenticide	510	110	[m^2]
$DEPTH_{soil}$:	Depth of exposed soil	0.1	0.1	[m]
RHO_{soil}:	Density of exposed soil	1700	1700	[$kg.m^{-3}$]
OUTPUTS				
$Elocal_{soil\text{-}campaign,\ direct}$:	*Direct emission to soil from a campaign*	1.00E-03	2.00E-04	[$g.camp^{-1}$]
$Elocal_{soil\text{-}campaign,\ indirect}$:	*Indirect emission to soil from a campaign*	8.91E-02	1.78E-02	[$g.camp^{-1}$]
$Elocal_{soil\text{-}campaign}$:	*Total emission to soil from a campaign*	9.01E-02	1.80E-02	[$g.camp^{-1}$]

$Clocal_{soil-D}$	*Local concentration in soil due to direct release ($AREA_{exposed-D}$) after a campaign:*	6.54E-03	1.31E-03	[$mg.kg^{-1}_{wwt}$]
$Clocal_{soil-ID}$	*Concentration in soil due to indirect (disperse= $AREA_{exposed-ID}$) release after a campaign:*	1.19E-03	9.53E-04	[$mg.kg^{-1}_{wwt}$]
$Clocal_{soil}$	***Worst case total concentration in soil =* $Clocal_{soil-D}$ + $Clocal_{soil-ID}$ = *PECsoil***	**7.49E-03**	**2.26E-03**	**[$mg.kg^{-1}_{wwt}$]**
$Clocal_{soil\ mean\ concentration}$	***Mean concentration in soil. The total amount of product release (=$Elocal_{soil-campaign}$) is divided by the whole area exposed(=$AREA_{exposed-ID}$)***	**9.64E-04**	**9.64E-04**	**[$mg.kg^{-1}_{wwt}$]**
Kp_{soil}	*Partition coefficient solid-water in soil*	1.83E+02	1.83E+02	[$L.kg^{-1}$]
$K_{soil\ water}$	*Soil-water partitioning coefficient*	2.75E+02	2.75E+02	[$m^3.m^{-3}$]
$PEClocal_{soil, porew}$	***Worst case concentration in groundwater (based on the total concentration in soil)***	**4.63E-05**	**1.40E-05**	**[$mg.L^{-1}$]**
$PEClocal_{soil, porew}$	***Mean concentration in groundwater (based on mean concentration in soil)***	**5.96E-06**	**5.96E-06**	**[$mg.L^{-1}$]**

2.2.7.4.3.2 OPEN AREAS

FANGA B+ BLOC P is applied in open areas inside or near the openings of the tunnels of the target rodents. According to the ESD PT14, the use near the openings of the tunnels demanding the use of bait boxes is covered by the assessment of the scenario “in and around buildings”. Thus this section “Open areas” only assesses the use inside the tunnels during which, according to the scenario presented in ESD PT14, 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. This scenario is worst case as the product FANGA B+ BLOC P is intended to be applied in secured bait boxes only.

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

Table 8: PEC of brodifacoum in soil for uses in open area

			Rat treatment	Mice treatment	unit
INPUTS	Qprod:	Amount of product used in control operation	200	40	[$g.burrow^{-1}$]
	$Fc_{product}$:	Fraction of active substance in product	0.01	0.01	[g a.i. kg^{-1}]
	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	[-]
	$Vsoil_{exposed}$:	Soil volume exposed to rodenticide	0.0085	0.0085	[m^3]
	RHO_{soil}:	Density of wet exposed soil	1700	1700	[$kg.m^{-3}$]
	Koc	Organic carbon adsorption coefficient	9155	9155	[$L.kg^{-1}$]
OUTPUTS	$Elocal_{soil-campaign}$	*Local emission of active substance to soil during a campaign*	1.00E-03	2.00E-04	[g.camp]
	$Clocal_{soil}$	*Local concentration in soil after a campaign*	6.92E-02	1.38E-02	[$mg.kg^{-1}_{wwt}$]

2.2.7.4.3.3 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 B+ BLOC P is intended to be used in bait boxes containing 200 g of biocidal product (0.001%) with 5 m spacing. So to predict the concentration of bromadiolone in soil and groundwater for the uses in waste dump, the intended doses are calculated for the 1 ha surface as below:

Q_{prod} = (length of the waste dump of 1ha/distance between bait) + 1) x (length of the waste dump of 1ha/distance between bait) x (amount of product per bait point)
Q_{prod} = ((100 m /5 m) + 1) x (100 m / 5 m) x 0.2 $kg_{product}$
Q_{prod} = 84 kg/ha

The ESD PT14 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 9: 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	[$kg.ha^{-1}$]
	$Fc_{product}$	Fraction of active substance in product	0.01	0.01	[g $a.i.kg^{-1}$]
	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^2]
	$DEPTH_{soil}$	Depth of exposed soil	0.1	0.1	[m]
	RHO_{soil}	Density of wet exposed soil	1700	1700	[$kg.m^{-3}$]
	Koc	Organic carbon adsorption coefficient	9 155	9 155	[$L.kg^{-1}$]
OUTPUT	**$Elocal_{soil-campaign}$**	*Local emission of active substance to soil from a campaign*	2.5	5.3	[$g.camp^{-1}$]

	Clocal$_{soil}$	*Local concentration in soil after a campaign*	1.48E-03	3.11E-03	[mg.kg$^{-1}_{wwt}$]
	Kp$_{soil}$	*Partition coefficient solid-water in soil*	1.83E+02	1.83E+02	[L.kg^{-1}]
	K$_{soil\ water}$	*Soil-water partitioning coefficient*	2.75E+02	2.75E+02	[m^{3}.m^{-3}]
	PEClocal $_{soil, porew}$	*Concentration in groundwater*	9.17E-06	1.93E-05	[mg.L^{-1}]

2.2.7.4.3.4 SEWERS

From the sewer use, an indirect exposure to soil via the STP sludge spreading on land is possible. PECsoil and subsequent concentrations in groundwater (porewater) are presented in the table below.

Table 10: PEC of brodifacoum in soil and groundwater for uses in sewer

Symbol	Variable/parameters	Worst case	Unit
$Q_{prod:}$	Amount of product used	30	[kg.camp^{-1}]
$Fc_{product}$:	Fraction of active substance in product	0.01	[g_{ai}.kg $^{-1}$]
DT_{50}	Half-life time in soil	298	d^{-1}
Temission	Number of emission days (realistic worst case during the control operation)	7	[d^{-1}]
$F_{released}$	Fraction released	0.9	[-]
SLUDGRATE	Sludge production rate	710	[kg.d^{-1}]
F $_{STP\ sludge}$	Fraction of emission directed to sludge by STP	0.511	[-]
$Elocal_{STP}$	*Local emission rate to the STP*	3.86E-05	[kg.d^{-1}]
Csludge (eq.36)	*Concentration in dry sewage sludge*	2.78E-02	[mg.kg^{-1}]
Csludge $_{soil\ 1}$ (0) (eq.60)	*Concentration in agric. soil in first year at T0*	4.08E-05	[mg.kg^{-1}]
C sludge $_{soil}$ 10 (0) (eq.62)	*Initial concentration in agric.soil after 10 years*	7.12E-05	[mg.kg^{-1}]
C sludge soil 10 (30)	***Twa concentration in agric. soil after 10 years over 30 days***	**6.87E-05**	**[mg.kg^{-1}]**
C sludge soil 10 (180)	*Twa concentration in agric. soil after 10 years over 180 days*	5.81E-05	[mg.kg^{-1}]
PEC $_{soil\ porewater}$ (eq.67)	***Concentration in porewater***	**3.59E-07**	**[mg.L^{-1}]**

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

2.2.7.4.4.1 PRIMARY POISONING

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.

Primary poisoning - Tier 1 assessment

The Tier 1 assessment assumes that the whole day's food requirement is satisfied by consumption of bait and therefore the concentration in food will be the same as the concentration of the active substance in the bait: 10 $mg.kg^{-1}$ (0.001% w/w of brodifacoum in FANGA B+ BLOC P). Hence, **the worst case Tier 1 PEC $_{oral}$ is 10 $mg.kg^{-1}$**.

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 11: PECoral 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 (%)	Bromadiolone conc. potentially ingested by non-target vertebrates (mg/kg) ≡ PECoral
100	10
50	5
40	4
30	3
20	2
10	1
5	0.5
2	0.2
1	0.1

Primary poisoning - Tier 2 assessment, acute exposure

According to ESD PT14, a Tier 2 assessment can be done estimating a daily uptake of a compound (ETE, $mg.kg^{-1}_{bw}.d^{-1}$) by non-target animals according to the equation 19 of ESD PT14:

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

With:

ETE is the estimated daily uptake of the active substance ($mg.kg^{-1}_{bw}.d^{-1}$),
FIR: food intake rate of the indicator species ($g.d^{-1}$),
BW: indicator species body weight (g),
C: concentration of the active substance in fresh diet ($mg.kg^{-1}$),
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 12: 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 mammal	BW (g)[a]	FIR ($g_{dry\ weight}.day^{-1}$)	C ($mg.kg^{-1}$)	ETE = concentration of brodifacoum after one meal ($mg.kg^{-1}_{bw}.d^{-1}$)	
				Step 1	Step 2
Dog	10 000	456[b]	10	0.46	0.33
Pig	80 000	600[a]	10	0.08	0.05
Pig, young	25 000	600[a]	10	0.24	0.17
Tree sparrow	22	7.6[a]	10	3.45	2.49
Chaffinch	21.4	6.42[a]	10	3.00	2.16
Wood pigeon	490	53.1[a]	10	1.08	0.78
Pheasant	953	102.7[a]	10	1.08	0.78

[a] From ESD PT14, Table 3.1, Section 3.2.1.
[b] From ESD PT14, using the equation log FIR = 0.822 log BW – 0.629 (for mammals)

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 are calculated by using the dose of the substance consumed by a non-target animal each day (ETE) using the realistic worst case scenario (Step 2), calculated above. When calculating the long-term risks, elimination and metabolism of the substance (El) have to be considered. Calculations are performed according to the equation 20 of the ESD PT14.

EC = ETE*(1-El)

According to the ESD PT14, a default value of 0.3 for daily uptake eliminated (El) can be used if no studies are submitted. The EC values are the expected concentration of active substance brodifacoum in non-target animals in primary poisoning scenarios after one meal followed by 24 hour elimination period.

Table 13: Expected concentrations of brodifacoum in non-target animals in realistic worst case (Step 2) for long-term situation.

Non-target animal	PEC: EC, concentration of brodifacoum after one day elimination (mg/kg)
Dog	0.23
Pig	0.04
Pig, young	0.12
Tree sparrow	1.74
Chaffinch	1.51
Wood pigeon	0.55
Pheasant	0.54

2.2.7.4.4.2 SECONDARY POISONING

Secondary poisoning via the aquatic food chain

For the sewer scenario, the contamination of the food chain via the contaminated aquatic compartment is likely after the STP. These PEC values for the aquatic compartment are therefore reported in table below, according to equation 89 of Guidance of BPR Vol. IV Part B.

According to the Guidance of BPR Vol. IV Part B, the most appropriate scenario is that 50% of the diet comes from a local area and 50% comes from the regional area, therefore a factor of 2 has to be applied to calculate PEC in food via aquatic food chain.

Table 14: PEC in food via aquatic chain

	Default values	Unit
Clocal water: local concentration in surface water	9.25E-07	[$mg.L^{-1}$]
BMF: biomagnification factor	10	[-]
BCF_{fish}: bioconcentration factor	35 645	[$L.kg_{wwt}^{-1}$]
PEC in food via aquatic food chain	1.65E-01	mg/kg wet fish

Secondary poisoning via the terrestrial food chain

IN AND AROUND BUILDING

According to the Guidance of BPR Vol. IV Part B, 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. 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 (Guidance of BPR Vol. IV Part B):

$$\mathbf{PEC\ oral,\ _{predator} = C\ _{earthworm}}$$

$$\mathbf{C\ _{earthworm} = (BCF\ _{earthworm} * C\ _{porewater}) + C\ local\ _{soil\ mean\ concentration} * F\ _{gut} * CONV\ _{soil}) / (1+F_{gut} * CONV\ _{soil})}$$

With (example for rat treatment application for in and around building application):

$BCF_{earthworm}$ = 15 820 $L.kg_{wet\ earthworm}^{-1}$,

$C_{porewater}$ = 7.45 E-06 $mg.L^{-1}$ (based on mean concentration in soil)

$C\ local_{soil\ mean\ concentration}$ = 1.20E-04 $mg.kg^{-1}_{wwt}$,

F_{gut} = 0.1 $Kg_{dwt}.kg_{wwt}^{-1}$,

$CONV_{soil}$ = 1.13 $Kg_{wwt}.kg\ d_{wt}^{-1}$,

According to the Guidance of BPR Vol. IV Part B, 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 local, soil is used in calculation, the PEC oral, predator to be used in risk assessment is $C_{earthworm}$ x 0.5.

Table 15: Expected concentrations of brodifacoum in predator

	PEC oral, $_{predator}$ mg/kg $_{wet\ earthworm}^{-1}$
	In and around building
TIER I: Worst case (based on the total concentration in soil)	
Rat treatment	3.40E-01
Mice treatment	9.94E-02
TIER I: Mean (based on the mean concentration in soil)	
Rat treatment	5.30E-02
Mice treatment	4.24E-02
TIER II: Mean (based on the mean concentration in soil) + considering degradation in soil (twa over 180 d with DT50 soil=298)	
Rat treatment	5.12E-02
Mice treatment	4.10E-02

IN SEWERS

For the sewer scenario, the contamination of the food chain *via* the contaminated terrestrial is possible after the STP These PEC values for the terrestrial compartment are therefore reported in table below.

According to the Guidance of BPR Vol. IV Part B, 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 local, soil is used in calculation, the PEC oral, predator to be used in risk assessment is $C_{earthworm}$ x 0.5.

Table 16: PEC in food via terrestrial chain

	Default values	**Unit**
C sludge soil 10: concentration in agric. soil after 10 years – Twa over 180 days	5.81E-05	[mg.kg-1]
PEC soil porewater: Concentration in porewater	3.59E-07	[mg.L-1]
BCFeartworm: bioconcentration factor	15820	[L.kgwwt-1]
PEC in food via terrestrial food chain	2.56E-03	mg/kg wet earthworm

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

According to the ESD PT14 document, for uses 'in and around buildings', 'open areas' and 'waste dumps', 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.

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 PECoral is then compared to the LC50 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) is 1, which means no avoidance, since rats is their natural prey, and the fraction of diet (PT) obtained in the area is set to 1.

The calculation is done according to equation 19 in the ESD:

ETE = (FIR/BW) * C * AV * PT * PD (mg $_{brodifacoum}$.kg $_{bw}^{-1}$.day^{-1})

This equation gives the concentration of brodifacoum in the rat (PECoral) after a meal the first day. Considering the elimination rate and that the mean time to death is seven days the concentration in the rodents each day can be calculated by the equation 21 in the ESD:

$$EC_n = \sum_{n=1}^{n-1} ETE * (1 - EL)^n$$

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

Table 17: Residues of brodifacoum in target animals at specific point in times and varying bait consumption

	Residues in target animal (mg.kg^{-1} bw)		
	20%	**50%**	**100%**
Day 1 after the first meal	0.20	0.50	1.00
Day 2 before new meal	0.14	0.35	0.70
Day 5 after the last meal	0.55	1.39	2.77
Day 7 mean time to death	0.27	0.68	1.36

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

Secondary poisoning - Tier 1 assessment, long-term

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 18: 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^{-1} $_{bw}$),** **ESD default values**
Day 5 after the last meal	2.77

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 2.77 $mg.kg^{-1}$ bw for rodents caught on day 5 and 3.31 $mg.kg^{-1}$ 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 19: 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 0.001%). Rodents fed 100% on rodenticide and predators/carnivores fed 50% on poisoned rodents

			Normal susceptible rodents caught on day 5		**Resistant rodents caught on day 14**	
Species	**Body weight (g)**	**Daily mean food intake ($g.d^{-1}$)**	**Amount a.i. (mg)[1]**	**Conc. ($mg.kg^{-1}$)[2]**	**Amount a.i. (mg)[1]**	**Conc. ($mg.kg^{-1}$)[2]**
Barn owl *(Tyto alba)*	295	72.9	0.10	0.34	0.12	0.41
Kestrel *(Falco tinnunculus)*	209	78.7	0.11	0.52	0.13	0.62
Little owl *(Athene noctua)*	164	46.4	0.06	0.39	0.08	0.47
Tawny owl *(Strix aluco)*	426	97.1	0.13	0.32	0.16	0.38
Fox *(Vulpes vulpes)*	5700	520.2	0.72	0.13	0.86	0.15
Polecat *(Mustela putorius)*	689	130.9	0.18	0.26	0.22	0.31
Stoat *(Mustela erminea)*	205	55.7	0.08	0.38	0.09	0.45
Weasel *(Mustela nivlis)*	63	24.7	0.03	0.54	0.04	0.65

[1] Amount a.i. consumed by non-target animal
[2] Conc. in non-target animal

2.2.7.5 Risk characterisation for the environment

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_{50}) according to the guidance in Technical guidance document (Guidance of BPR Vol. IV Part B, 2003) and "Emission Scenario document for biocides used as rodenticides" (ESD PT14).

The environmental risk characterization has been carried out for brodifacoum.

2.2.7.5.1 Aquatic compartment (including water, sediment and STP)

2.2.7.5.1.1 SEWERS

The **Erreur ! Source du renvoi introuvable.** below presents PEC/ PNEC ratios for surface water, sediment nd STP for the use of FANGA B+ BLOC P in sewer systems:

Table 20: PEC/PNEC ratios for the aquatic compartment

	PEC	PNEC	PEC/PNEC	Risk

	Default values		Default values	
Surface water (mg/L)	9.25E-07	4.00E-05	2.31E-02	Acceptable
Sediment (mg/kg wwt)	1.85E-04	4.30E-02	2.31E-01	Acceptable
STP (mg/L)	9.37E-06	3.80E-03	2.47E-03	Acceptable

No unacceptable risk is identified for the aquatic compartment including surface water, sediment and STP when the FANGA B+ BLOC P is used in sewer system against rodents, even when no metabolisation of the active substance is considered. For sediment, according to the Guidance of BPR Vol. IV Part B and considering the log Kow > 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.

2.2.7.5.1.2 OTHER USES

Exposure scenario is not considered relevant in the ESD for rodenticides. Brodifacoum is not expected to occur to any significant extent following the use of FANGA B+ BLOC P in and around buildings, in open areas or in waste dump. Therefore, PEC values for brodifacoum in surface water and sediment are assumed to be negligible and have not been further considered.

2.2.7.5.2 Atmospheric compartment

Due to its physico-chemical properties (low vapour pressure of 2.6 x 10^{-22} Pa at 20°C and low Henry's law constant of 2.35 x 10^{-18} $Pa.m^3.mol^{-1}$), 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 B+ BLOC P biocidal product.

2.2.7.5.3 Terrestrial compartment (including soil and groundwater)

Soil exposure occurs both through a combination of direct and indirect releases from the use of FANGA B+ BLOC P bait in the scenario 'in and around buildings', 'open areas', 'waste dump' and 'sewers'.

2.2.7.5.3.1 SEWERS

The Table 22 below presents PEC/ PNEC ratios for soil and groundwater for the use of FANGA B+ BLOC P in sewer systems:

Table 21: PEC/PNEC ratios for the terrestrial compartment

	PEC	PNEC or threshold value	PEC/PNEC	Risk
	Default values		Default values	
Soil(mg/kg_{wwt})	6.87E-05	8.80E-01	7.81E-05	Acceptable
Groundwater (mg/L)	3.59E-07	1.00E-04*	Threshold value	Acceptable

The risk is acceptable for the terrestrial compartment when FANGA B+ BLOC P is used in sewer systems.

2.2.7.5.3.2 IN AND AROUND BUILDING

Exposure of the terrestrial compartment (soil) will occur when FANGA B+ BLOC P is deployed outdoors.
Realistic worst case predicted soil concentrations (PECs) have been calculated for the use scenario in and around buildings, for application in control campaign. The resulting PEC/PNEC ratios for the worst case scenario (addition of direct and indirect exposure) for the soil are summarized in the table below:

Table 22: PECsoil/PNECsoil for soil organisms exposed to brodifacoum following outdoor use of bait around buildings

Baiting scenario (ESD PT14)	**PECsoil (mg $_{brodifacoum}$.kg $_{wwt}$ $soil^{-1}$)**	**PNECsoil (mg $_{brodifacoum}$.kg $_{wwt}$ $soil^{-1}$)**	**PEC/PNEC ratio**

Realistic worst case			
Rat treatment	7.49E-03	0.88	8.51E-03
Mice treatment:	2.26E-03		2.57E-03

The PEC/PNEC ratios are below 1 indicating no unacceptable risks to the terrestrial compartment when the product FANGA B+ BLOC P is used in and around building.

The risk is acceptable in groundwater for the use of FANGA B+ BLOC P in and around building as presented below:

Table 23: PEC groundwater due to use of FANGA B+ BLOC P in and around building

Baiting scenario (ESD PT14)	**PEC groundwater ($\mu g_{brodifacoum}.L^{-1}$)**	**Threshold value in groundwater ($\mu g.L^{-1}$)**	**Risk characterization**
Realistic worst case			
Rat treatment	4.63E-02	0.1	Acceptable
Mice treatment	1.40E-02		

2.2.7.5.3.3 OPEN AREAS

Exposure of the terrestrial compartment (soil) will occur when FANGA B+ BLOC P bait is applied in open areas by inserting inside the openings of the tunnels of the target rodents.

Predicted soil concentrations (PECs) have been calculated for the use scenario in open areas, for application in rats/rodents control campaign according to the doses claimed by the applicant. The resulting PEC/PNEC ratios for the soil are summarized in the table below:

Table 24: PECsoil/PNECsoil for soil organisms exposed to brodifacoum following use of bait in open area

Baiting scenario (EUBEES 2)	**PEC_{soil}** (mg /kg wwt)	**$PNEC_{soil}$** (mg /kg wwt)	**PEC/PNEC**
Typical use (rat treatment)	6.92E-02	0.88	0.079
Typical use (mice treatment)	1.38E-02		0.016

The PEC/PNEC ratios are below 1 and indicate that there are no unacceptable risks to the terrestrial compartment when the product FANGA B+ BLOC P is used in the tunnels of open areas. According to the scenario, the use near the openings of the tunnels is covered by the assessment of the scenario “in and around buildings” with bait box. As argued above (section above 2.2.7.5.3.2), there is no unacceptable risk for the terrestrial compartment (including groundwater) when the FANGA B+ BLOC P is used near the openings of the tunnels of the target rodents.

2.2.7.5.3.4 “THE EMISSION TO SOIL, LEADING TO GROUNDWATER CONTAMINATION BY LEACHING, FOR THE USE IN OPEN AREA, IS LOWER THAN IN THE SCENARIO WASTE DUMP. THUS THE RISK FOR GROUNDWATER DUE TO THE USE IN OPEN AREA IS COVERED BY THE ONE FOR THE WASTE DUMP SCENARIO.”WASTE DUMP

Predicted soil concentrations (PECs) have been calculated for the use scenario in waste dump. The resulting PEC/PNEC ratios for the soil are summarized in the Table below:

Table 25: PECsoil/PNECsoil for soil organisms exposed to brodifacoum following use of bait at waste dumps

Baiting scenario (ESD PT14)	PECsoil (mg $_{brodifacoum}$.kg $_{wwt}$ soil^{-1})	PNECsoil (mg $_{brodifacoum}$.kg $_{wwt}$ soil^{-1})	PEC/PNEC ratio
Rat treatment (40 kg.ha^{-1})	1.48E-03	0.88	0.002
Rat treatment (84 kg.ha^{-1})	3.11E-03	0.88	0.004

The PEC/PNEC ratios are below 1 indicating that there no unacceptable risks to the terrestrial compartment when the product FANGA B+ BLOC P is used in waste dump.

Table 26: PEC groundwater due to use of FANGA B+ BLOC P in waste dump

Baiting scenario (ESD PT14)	PEC groundwater (µg $_{brodifacoum}$.L^{-1})	Threshold value in groundwater (µg.L^{-1})	Risk characterization
Rat treatment (40 kg.ha^{-1})	9.17E-03	0.1	Acceptable
Rat treatment (84 kg.ha^{-1})	1.93E-02		Acceptable

The risk for groundwater is acceptable.

2.2.7.5.4 Non-compartmental specific effects relevant to the food chain

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_{50}) according to the guidance in Technical guidance document (Guidance of BPR Vol. IV Part B) and "Emission Scenario document for biocides used as rodenticides" (ESD PT14).

The environmental risk characterization has been carried out for brodifacoum.

Bait containing brodifacoum contains also 50 mg denatonium benzoate per kg, a powerful bittering agent that is intended to deter accidental ingestion of blocks or gains by humans. It may also deter some non-target mammals.

2.2.7.5.4.1 PRIMARY POISONING

Tier 1 assessment

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

Table 27: Tier 1 risk characterization of primary poisoning – Long-Term

	PEC[1] mg.kg food^{-1}	**PNEC[1]** mg.kg food^{-1}	**PEC/PNEC**
Mammals	10	2.22E-04	**45045**
Birds	10	1.30E-04	**76923**

[1] Concentration of brodifacoum in food.

The resulting PEC/PNEC ratio reveals a high risk of long-term primary poisoning for mammals.

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. The PNEC for birds has been used as a worst case in the calculations.

Table 28: PEC oral/ PNEC $_{oral}$ for non-target, birds exposed to brodifacoum in bait removed from secured bait points in and around buildings

Fraction of ingested food (%)	PECoral mg.kg food^{-1}	PNEC mg.kg food^{-1}	PEC/PNEC
100	10	1.30E-04	**76 923**

50	5		**38 462**
40	4		**30 769**
30	3		**23 077**
20	2		**15 385**
10	1		**7 692**
5	0.5		**3 846**
2	0.2		**1 538**
1	0.1		**769**

The long-term assessment indicates clearly unacceptable risks even if only 1% of the food is constituted of bait. The risk is, however, mitigated by the prerequisite that good practice requires that secured bait points, containing bait in a chamber not directly accessible from the access hole, be used in locations where a potential for avian exposure exists.

Tier 2 assessment, acute exposure

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_{50} value.

Table 29: Tier 2 acute qualitative risk assessment of primary poisoning

	PEC_{oral}[1] mg.kg^{-1} bw		**LD_{50} dose** mg.kg^{-1} bw d^{-1}	**PEC_{oral} > LD_{50} (y/n)**	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	3.45	2.49	0.31	y	y
Chaffinch	3.00	2.16		y	y
Wood pigeon	1.08	0.78		y	y
Pheasant	1.08	0.78		y	y
Dog	0.46	0.33	0.4	y	n
Pig	0.08	0.05		n	n
Pig young	0.24	0.17		n	n

[1] PEC_{oral} = ETE, concentration of brodifacoum after one meal

The qualitative approach for the acute situation confirms the potential risk of primary poisoning to birds and dogs. The level of the risk is not clarified for all other species with this approach, as a PEC below the LD50 does not indicate the absence of unacceptable risk if the required margin of safety is not established

Tier 2 assessment, long-term exposure

The PEC values for the Tier 2 assessment of the long-term exposure are compared to the PNEC values.

Table 30: Tier 2 long-term risk assessment: PECoral/PNECoral for non-target animals in realistic worst case (step 2) for long-term situation

Non-target animal	**PEC_{oral}**[1] mg.kg^{-1} bw	**PNEC** mg.kg^{-1} bw d^{-1}	**PEC/PNEC**
Dog	0.23	1.10E-05	**20 909**
Pig	0.04		**3 636**
Pig, young	0.12		**10 909**
Tree sparrow	1.74	1.30E-05	**133 846**
Chaffinch	1.51		**116 154**
Wood pigeon	0.55		**42 308**
Pheasant	0.54		**41 538**

[1] PEC_{oral} = EC, concentration of brodifacoum after one day of elimination

This assessment provides indication of very high risks to both mammals and birds, but, it should be noted that consumption of these quantities of brodifacoum bait is generally not realistic and should be regarded strictly as worst case.

2.2.7.5.4.2 SECONDARY POISONING

Secondary poisoning via the aquatic food chain

As no exposure of the aquatic compartment is foreseen with the use of FANGA B+ BLOC P for the uses in and around buildings, in open areas and in waste dumps, no risk assessment for secondary poisoning through the aquatic food chain is required.

For the sewer scenario, the contamination of the food chain via the contaminated aquatic compartment is possible after the STP according to EUSES 2.1.0. These PEC/PNEC values for the aquatic compartment are therefore reported in table below.

Table 31: Secondary poisoning via aquatic food chain in sewer system

	Aquatic $PEC_{oral,predator}$ mg/kg wet	**$PNEC_{oral}$ mg/kg food**	**Aquatic PEC/PNEC**
	Default values		**Default values**
Birds	1.65E-01	1.30E-04	1.27E+03
Mammals		2.22E-04	7.42E+02

The risks for secondary poisoning are unacceptable via the aquatic food chain in the sewer system for birds and mammals.

Secondary poisoning via the terrestrial food chain

SEWER

The $PEC_{oral\ predator}$ values are compared to the long-term PNEC for mammals and for birds.

Table 32: Secondary poisoning via terrestrial food chain in sewer system

	Terrestrial $PEC_{oral,\ predator}$ mg/kg wet	**$PNEC_{oral}$ µg/kg food**	**Terrestrial PEC/PNEC**
	Default values		**Default values**
Birds	2.56E-03	1.30E-05	1.97E+01
Mammals		2.22E-04	1.15E+01

The risks for secondary poisoning are unacceptable via the terrestrial food chain in the sewer system for birds and mammals.

IN AND AROUND BUILDINGS

Secondary poisoning for the earthworm-eating mammal or the earthworm-eating bird

Table 33: risk characterization of secondary poisoning via the terrestrial food chain

	PEC oral, $_{predator}$ mg/kg $_{wet\ earthworm}^{-1}$	**$PNEC_{oral}$** mg.kg $_{food}^{-1}$		**PEC/PNEC**	
	ESD Default parameters	**Mammals**	**Birds**	**ESD Default parameters**	
				Mammals	**Birds**
TIER I: Worst case (based on the total concentration in soil)					
Rat treatment	3.40E-01	2.22E-04	1.30E-04	**1 532**	**2 615**

Mice treatment	9.94E-02			**448**	**765**
TIER I: Mean (based on the mean concentration in soil)					
Rat treatment	5.30E-02	2.22E-04	1.30E-04	**239**	**408**
Mice treatment	4.24E-02			**191**	**326**
TIER II (based on time-weight average concentration (180d) in soil)					
Rat treatment	5.12E-02	2.22E-04	1.30E-04	**231**	**394**
Mice treatment	4.10E-02			**185**	**315**

Whatever the scenario, the PEC/PNEC ratio exceeds 1 for both earthworm eating birds and mammals.

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

Tier 1 assessment, acute

The PEC_{oral} are compared to the LC_{50} value presented in the section above for a qualitative risk assessment in accordance with the decisions taken at the TMII-06.

Table 34: Tier 1 long-term risk assessment of secondary poisoning

Non-target animal	**PECoral** $mg.kg^{-1}_{bw}$			**LC_{50} dose** $mg.kg^{-1}_{food}$	**PEC_{oral} > LC_{50} (y/n)**		
	PD=0.2	PD=0.5	PD=1		PD=0.2	PD=0.5	PD=1
Birds	0.55	1.39	2.77	8	n	n	n
Mammals	2.8	6.9	13.9	0.72	**y**	**y**	**y**

[1] PEC_{oral} = Expected concentration in rodent caught on day 5 after meal
PD = fraction of the food type in the diet

This qualitative risk assessment indicates no risk for birds 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 PNECoral for birds and mammals.

Table 35: Tier 1 long-term risk assessment of secondary poisoning

Non-target animal	**PECoral** $mg.kg^{-1}_{bw}$	**PNEC** $mg.kg^{-1}_{food}$	**PEC /PNEC**
Birds	2.77	1.30E-04	**21 308**
Mammals	2.77	2.22E-04	**12 477**

PEC_{oral} = 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 36: 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
Barn owl *(Tyto alba)*	0.34	0.41	1.30E-05	**26447**	**31574**
Kestrel *(Falco tinnunculus)*	0.52	0.62		**40162**	**47949**
Little owl *(Athene noctua)*	0.39	0.47		**30176**	**36027**
Tawny owl *(Strix aluco)*	0.32	0.38		**24311**	**29024**
Fox *(Vulpes vulpes)*	0.13	0.15	1.10E-05	**11504**	**13734**
Polecat *(Mustela putorius)*	0.26	0.31		**23948**	**28590**
Stoat *(Mustela erminea)*	0.38	0.45		**34249**	**40889**
Weasel *(Mustela nivlis)*	0.54	0.65		**49420**	**59001**

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

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 section 2.9.

2.2.8 Measures to protect man, animals and the environment

Please refer to summary of the product assessment and to the relevant sections of the assessment report.

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Annex 0: Practical use of Biocides ex:TP14

Name of the product and type of formulation (grains, powder, paste, block…)	Target organism (rat, mice…)*	User category (professional/non professional)*	Area of use (sewers, in and around buildings, indoor only, open areas, waste dumps,…)*	Dosage claimed expressed in g/bait point, for high and low infestation (if appropriate)	Time delay of the action of the product	Frequency and method of controls	Size(s) of the bait (g/bloc, g/grain, g/sachet, g/paste …)	Distance between 2 bait points, for high and low infestation (if appropriate)	Methods of application of the bait (ex: pre-filled secured bait box)	Package details : Individual packaging (yes/no)**	Primary packaging : type : bulk, individual wrapping…/ nature: bucket, bottle, sachet…/ material: paper, polyethylene…/ sizes	Secondary packaging	Accepted and authorised by the
FANGA B+ BLOC P Formulation: BLOCK	Brown rat: *Rattus norvegicus*	Professionnal	In and around buildings, open areas, waste dumps, landfills, sewers	180-200 g/secured bait point		4 refilling of bait stations Over 28 days Interval between applications (min) : one week	4 - 20 - 25 - 30-40- 50 - 100g sachet	5-10 meters	Manual application of baits in bait stations	yes	Sachet PE or PP	Bag (paper bags several layers with one or without plastic film in PE) 5-10-15-20-25 kg Bucket (PE) - 5-10-15-18-20 kg Carton box (carton) - 5-10-12-15-20-50 kg	
	Brown rat: *Rattus norvegicus*	Professionnal	In and around buildings, open areas, waste dumps, landfills, sewers	180-200 g/secured bait point		4 refilling of bait stations Over 28 days Interval between applications (min) : one week	4 to 200g blocks in bulk	5-10 meters	Manual application of baits in bait stations	no	bulk	Sachet PE or PP 100g - 200-300-400-500-600-700-800-900- 1000g packed in carton box 5-10-12-15-18- 20 kg Bag (paper bags several layers with one or without plastic film in PE) – 5-10-15-20-25 kg Bucket (PE) - 5-10-15-18-20-25 kg Carton box (carton) - 5-	

											10-12-15-20 -25-50kg	
	Brown rat*: Rattus norvegicus*	Non professionnal	In and around buildings , open areas	180-200 g/secured bait point		4 refilling of bait stations Over 28 days Interval between applications (min) : one week	4- 20 - 25 - 30-40- 50 - 100g sachet	5-10 meters	Pre-filled secured boxes Manual application of baits in bait stations	yes	Sachet PE or PP	Bucket (PE) – 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 box (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--1,5 kg Metal box (without lacquer) - 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1-1,2- 1,3-1,4-- 1,5 kg Bait box (plastic PET/PP/PE/PVC) dimensions 230 mm x 135 mm x 85 mm Flacon (PEHD) 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	
	Black rat: *Rattus rattus*	Professionnal	In and around buildings , open areas, waste dumps, landfills	180-200 g/secured bait point		4 refilling of bait stations Over 28 days Interval between applications (min) : one week	4- 20 - 25 - 30-40- 50 - 100g sachet	5-10 meters	Manual application of baits in bait stations	yes	Sachet PE or PP	Bag (paper bags several layers with one or without plastic film in PE) – 5-10-15-20-25 kg Bucket (PE) - 5-10-15-18-20 kg Carton box (carton) - 5-10-12-15-20-50 kg	
	Black rat: *Rattus rattus*	Professionnal	In and around buildings , open areas, waste dumps, landfills	180-200 g/secured bait point		4 refilling of bait stations Over 28 days Interval between applications (min) : one week	4 to 200g blocks in bulk	5-10 meters	Manual application of baits in bait stations	no	bulk	Sachets PE or PP100g - 200-300-400-500-600-700-800-900- 1000g packed in carton box from 5-10-12-15-18- 20 kg Bag (paper bags several layers with one or without plastic film in PE) – 5-10-15-20-25 kg Bucket (PE) - 5-10-15-18-20-25 kg Carton box (carton) - 5-10-12-15-20 -25-50kg	
	Black rat: *Rattus rattus*	Non professionnal	In and around buildings , open	180-200 g/secured bait point		4 refilling of bait stations Over 28 days Interval between	4 - 20 - 25 - 30-40- 50 - 100g sachet	5-10 meters	Pre-filled secured boxes Manual application of	yes	Sachet PE or PP	Bucket (PE) – 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 box (carton) – 0,1-	

			areas			applications (min) : one week			baits in bait stations			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 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 (plastic PET/PP/PE/PVC) dimensions 230 mm x 135 mm x 85 mm Flacon (PEHD) 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	
	Mice: *Mus musculus*	Professionnal	In and around buildings , open areas, waste dumps, landfills	30-40 g/secured bait point		4 refilling of bait stations Over 28 days Interval between applications (min) : one week	4 - 20- 30- 40g sachet	1-2 meters		yes	Sachet PE or PP	Bag (paper bags several layers with one or without plastic film in PE) – 5-10-15-20-25 kg Bucket (PE) - 5-10-15-18-20 kg Carton box (carton) - 5-10-12-15-20-50 kg	
	Mice: *Mus musculus*	Professionnal	In and around buildings , open areas, waste dumps, landfills	30-40 g/secured bait point		4 refilling of bait stations Over 28 days Interval between applications (min) : one week	4 to 40g blocks in bulk	1-2 meters	Manual application of baits in bait stations	no	bulk	Sachets PE or PP100g - 200-300-400-500-600-700-800-900- 1000g packed in carton box from 5-10-12-15-18- 20 kg Bag (paper bags several layers with one or without plastic film in PE) – 5-10-15-20-25 kg Bucket (PE) - 5-10-15-18-20-25 kg Carton box (carton) - 5-10-12-15-20 -25-50kg	
	Mice: *Mus musculus*	Non professionnal	In and around buildings , open areas	30-40 g/secured bait point		4 refilling of bait stations Over 28 days Interval between applications (min) : one week	4 - 20 - 30 - 40g sachet	1-2 meters	Pre-filled secured boxes Manual application of baits in bait stations	yes	Sachet PE or PP	Bucket (PE) – 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 box (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-- 1,5 kg Metal box (without lacquer) - 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1-	

												1,2- 1,3-1,4-- 1,5 kg Bait box (plastic PET/PP/PE/PVC) dimensions 127 mm x 65 mm x 35 mm Flacon (PEHD) 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	

Annex 1: Analytical methods residues – active substance

See details in section 2.2.4 of the PAR.

brodifacoum

Annex 2 : Toxicology and metabolism –active substance

< BRODIFACOUM >

Threshold Limits and other Values for Human Health Risk Assessment

Date: 16/06/2016

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

Inhalative absorption	100%
Oral absorption	75%
Dermal absorption	0.047%

Classification	
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Acute Tox 1 H330 Acute Tox 1 H310 Acute Tox 2 H300 STOT RE Cat 1 H372 (blood) Repr 1A H360D Specific limit concentrations Rep 1A – H360D C ≥ 0.003% STOT RE 1 – H372 (blood) C ≥ 0.02% STOT RE 2 – H373 (blood) 0.002% ≤ C > 0.02%

< FANGA B+ BLOC P>

Date: 16/06/2016

General information

Formulation Type	paste
Active substance(s) (incl. content)	Brodifacoum (0.0012% m/m)

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 None
Toxicological data on non-active substance(s) (not tested with the preparation)	None None
Further toxicological information	None

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Regulation 1272/2008/EC	None

Annex 4: Safety for professional operators

< FANGA B+ BLOC P>

Date: 16/06/2016

Exposure assessment

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

Primary exposure of professionals – FANGA B+ BLOC P – Control of rats

	Component	CAS	Actual Dermal Total [mg/kg/d]	Inhalation Exposure [mg/m³]	Model
Bulk formulation					
Professionnal rat (without gloves)	Brodifacoum	56073-10-0	1.58×10^{-6}	negligible	CEFIC study

Risk assessment – Professional

Scenario	Component	CAS	AEL [mg/kg/d]	Absorption [%]		Total syst exposure [mg/kg bw/d]		Risk
				inh	derm	Expo	%AEL	
Bulk formulation								
Professionnal rat (without gloves)	Brodifacoum	56073-10-0	3.3×10^{-6}	100	0.047	1.58×10^{-6}	48%	Acceptable

Annex 5: Safety for non-professional operators and the general public

< FANGA B+ BLOC P>

Date:16/06/2016

General information	
Formulation Type	paste
Active substance(s) (incl. content)	Brodifacoum (0.0012% m/m)

<Active Substance>

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

Exposure scenarios for intended uses (Annex IIIB, point 6.6)	
Primary exposure	CEFIC Study and HEEG opinion n°12
Secondary exposure, acute	Reverse scenario
Secondary exposure, chronic	na

Conclusion:

Exposure of non-professionals and the general public to the biocidal product containing 0.0012% as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

Primary exposure of non professionals – FANGA B+ – Control of rats

	Component	**CAS**	**Actual Dermal Total [mg/kg/d]**	**Inhalation Exposure [mg/m³]**	**Model**
Sachet formulation (PP or PE)					
Non Professionnal	Brodifacoum	56073-10-0	2.68×10^{-9}	negligible	CEFIC study

Risk assessment – Non -professional

Scenario	**Component**	**CAS**	**AEL [mg/kg/d]**	**Absorption [%]**		**Total syst exposure [mg/kg bw/d]**		Risk
				inh	derm	Expo	%AEL	
Sachet formulation (PP or PE)								
Non Professionnal	Brodifacoum	56073-10-0	3.3×10^{-6}	100	0.047	2.68×10^{-9}	0.04%	Acceptable

brodifacoum

Date: 17.11.2015

Intended Use: TP14 - Rodenticide against wild mice, brown rats and black rats.

Active substance: brodifacoum
Formulation of biocidal product: bait
Place of treatment: In and around buildings and open areas by professional and non professional users. In waste dumps and landfills by professional users.

The intended use descriptions of the brodifacoum-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used as bait stations and pre-fille secured boxes in and around buildings and open areas. No further data are required concerning the residue behaviour.

The intended uses are not relevant in terms of consumer health protection.

Annex 7: 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***
BDBP12V1 (FANGA B+ BLOC P) 0.0012% Brodifacoum	Black rat (*Rattus rattus*)	Laboratory study Method based on : Technical Notes for Guidance on Product Evaluation – Product type 14 Black rats: 10 animals (5 males and 5 females) Intoxication duration: 4 days.	Acclimation: 4 days in individual cage. Intoxication phase: Standard Laboratory diet was removed and replaced by the Test Bait (A) and Reference (Feed "bouchon" SAFE-04) (B) in two clean pots at the animals' disposal. Each day, the hoppers were weighted, readjusted and its places were inverted. Losses were also weighted. Daily bait consumptions were measured and the respective consumptions of bait were determined in relation with the body weight of animals. All used Test Bait and Reference is discarded and fresh quantities of each diet are placed in clean pot. In placing the pots back in the cage, the positions of the rodenticide and the reference diet should be interchanged to avoid place preference. This procedure will be repeated every day during the choice period.	The BDBP12V1 (FANGA B+ BLOC P) bait containing 12 ppm Brodifacoum given to 10 black rats (5 males and 5 females) during 4 days according to technical notes for guidance on product evaluation – product type 14 protocol has demonstrated that: - A mean palatability equivalent to 0.40 - A good consumption for all rats between D0 and D4 - A total efficacy, with 100% of	14TOX043[22]	*1*

[22] Guicherd A. 2015. Study on the palatability and efficacy of a 0.0012% w/w Brodifacoum Bloc bait in black Rat *(Rattus Rattus}. Biolytics,* Report 14TOX043of the 16 February 2015, not GLP..

			Post treatment phase: After day 4 the animals should be returned to the standard laboratory diet. Food and bait consumption were measured and mortality was observed during 20 days after the first day of intoxication.	mortality for males between D7 and D9 - and 100% of mortality for females in a period from D7 to D8 Efficacy can be considered as total for black rats.		
BDBP12V1 (FANGA B+ BLOC P) 0.0012% Brodifacoum	Brown rat (*Rattus norvegicus*)	Laboratory study Method: 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	Acclimatization: 4 days in individual cage at room temperature. Intoxication phase: 4 days Standard Laboratory diet was removed and replaced by the Test Bait (A) and Reference (Feed "bouchon" SAFE-04) (B) in two clean pots at the animals' disposal. Each day, the hoppers were weighted, readjusted and its places were inverted. Losses were also weighted. Daily bait consumptions were measured and the respective consumptions of bait were determined in relation with the body weight of animals. All used Test Bait and Reference is discarded and fresh quantities of each diet are placed in clean pot. In placing the pots back in the cage, the positions of the rodenticide and the reference diet should be interchanged to avoid place	The BDBP2V1 (FANGA B+ BLOC P) bait containing 12 ppm Brodifacoum given to brown rats (5 males and 5 females) during 4 days according to the Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products » has demonstrated: - A mean palatability equivalent to	Guicherd A. Study 15TOX002[23]	*1*

[23] Guicherd A. 2015. Study on the palatability and the efficacy of a 0.0012% (w/w) Brodifacoum block bait in brown rat (*Rattus norvegicus*). Biolytics, Study 15TOX002 of 16 February 2015, not GLP.

			preference. This procedure will be repeated every day during the choice period. Post-treatment phase: After day 4 the animals should be returned to the standard laboratory diet. Mortality was observed during 21 days every 24 hours.	0.43 - A good consumption for all rats between D0 and D4 - A total efficacy, with 100% of mortality for males between D4 and D7 and 100 % of mortality for females in a period from D6 to D7. Efficacy can be considered as total for brown rats.		
BDBP12V1 (FANGA B+ BLOC P) 0.0012% Brodifacoum	House mice (*Mus musculus*)	Laboratory study Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products » House mice:	Acclimatization: 4 days in separate cages (10 males in a cage and 10 females in a second cage) at room temperature. Treatment phase: Standard Laboratory diet was removed and replaced by the Test Bait (A) and Reference (Feed "bouchon" SAFE-04) (B) in two clean pots at the animals' disposal. Each day, the hoppers were weighted, readjusted and its places were inverted. Losses were also weighted. Daily bait consumptions were measured and the respective consumptions of bait were	The BDBP12V1 (FANGA B+ BLOC P) bait containing 12 ppm Brodifacoum given to house mice (10 males and 10 females) during 4 days according to the Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of	Guicherd A. Study 14TOX044[24]	*1*

[24] Guicherd A. 2014. Study on the palatability and efficacy of a 0.0012% Brodifacoum block bait in house mouse (*Mus musculus*). Biolytics, Study 14TOX044 of 23 December 2014, not GLP (unpublished).

		10 males and 10 females. Intoxication duration: 4 days.	determined in relation with the body weight of animals. All used Test Bait and Reference is discarded and fresh quantities of each diet are placed in clean pot. In placing the pots back in the cage, the positions of the rodenticide and the reference diet should be interchanged to avoid place preference. This procedure will be repeated every day during the choice period. Post treatment phase: After day 4 the animals should be returned to the standard laboratory diet. Mortality was observed during 21 days every 24 hours or until the death of all animals.	rodenticidal biocidal products » has demonstrated: • A mean palatability equivalent to 0.64 • A good consumption between D0 and D4 for males and females • A total efficacy, 100% of mortality for males in a period from D4 to D6 and 100% of mortality for females in a period from D1 to D9. Efficacy can be considered as total for house mice.		
BDBP12V1 (FANGA B+ BLOC P) 0.0012% Brodifacoum	Black rats (*Rattus rattus*)	Field test EPPO PP 1/114(2)	The trial was set up in an agricultural habitat (breeding stables for hens, fodder and equipment warehouses) in which rats infestation was signalled by the farmer. - 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	The trial was set up in an agricultural habitat (breeding stables for hens, fodder and equipment warehouses) in which rats infestation was signalled by the	Rovetto I. Study n°2018.BCD.SAG14[25]	*1*

[25] Rovetto I. 2015. Efficacy evaluation of BDBP12V1 (brodifacoum 0.0012% w/w a.i., block bait) against Roof rat (*Rattus rattus* L.) in Italy. SAGEA SR Centro di Saggio, Report n° 2018.BCD.SAG14 of 4 April 2015, GEP, unpublished.

			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 2014-11-19 to 2014-12-30	farmer. The farm site was surveyed and a notable presence of rats over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Roof rat (*Rattus rattus* L.). Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings. In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rat population size during a Pre-treatment *census* (monitoring of the daily consumption of unpoisoned *placebo* baits). On the same way it was calculated an index of the rat population size after		

				the Poisoning phase (monitoring of the daily consumption of unpoisoned placebo baits during the Post-treatment phase). According to the results of the present study, BDBP12V1 (FANGA B+ BLOC P) showed a good acceptance level and provided a complete effectiveness (100.0%) against the Rattus rattus population present across the trial site when used at the application rate of 200 g per bait station.		
BDBP12V1 (FANGA B+ BLOC P) 0.0012% Brodifacoum	Brown rats (*Rattus norvegicus*)	Field test EPPO PP 1/114(2)	The trial was set up in an agricultural habitat (cow breeding stables, fodder and equipment warehouses) in which rats infestation was signalled by the farmer. - Method for recording / scoring effects: daily bait take and tracking score during the trial period	The trial was set up in an agricultural habitat (cow breeding stables, fodder and equipment warehouses) in which rats infestation was	Rovetto I. Study n°2017.BCD.SAG14[26]	*1*

[26] Rovetto I. 2015. Efficacy evaluation of BDBP12V1 (brodifacoum 0.0012% w/w a.i., block bait) against Norway rat (*Rattus norvegicus* L.) in Italy. SAGEA SR Centro di Saggio, Report n° 2017.BCD.SAG14 of 4 April 2015, GEP, unpublished.

			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 2014-11-19 to 2014-12-30	signalled by the farmer. The farm site was surveyed and a notable rats presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Norway rat (*Rattus norvegicus* Berk.). Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings. In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rat population size during a Pre-treatment *census* (monitoring of the daily consumption of unpoisoned *placebo* baits). On the same way it was calculated an		

				index of the rat population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned *placebo* baits during the Post-treatment phase). According to the results of the present study, BDBP12V1 (FANGA B+ BLOC P) showed a good acceptance level and provided a complete effectiveness (100.0%) against the Rattus norvegicus population present across the trial site when used at the application rate of 200 g per bait stations.		
BDBP12V1 (FANGA B+ BLOC P) 0.0012% Brodifacoum	House mouse (*Mus musculus*)	Field test EPPO PP 1/114(2)	The trial was set up in an agricultural habitat (cows breeding stable, fodder and equipment warehouse) in which mice infestation was signalled by the farmer - Method for recording / scoring effects:	The trial was set up in an agricultural habitat (cows breeding stable, fodder and equipment	Rovetto I. Study n°2016.BCD.SAG14[27]	*1*

[27] Rovetto I. 2015. Efficacy evaluation of BDBP12V1 (brodifacoum 0,0012% w/w a.i., block bait) against House mouse (*Mus musculus* L.) in Italy. SAGEA SR Centro di Saggio, Report n° 2016.BCD.SAG14 of 4 April 2015, GEP, unpublished.

			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 mice 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 2014-11-19 to 2014-12-30	warehouse) in which mice infestation was signalled by the farmer. The farm site was surveyed and a notable mice presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these mice to be identified as belonging to *Mus musculus* 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 mice population size during a Pre-treatment *census* (monitoring of the daily consumption of unpoisoned *placebo* baits).		

				On the same way it was calculated an index of the mice population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned *placebo* baits during the Post-treatment phase). According to the results of the present study, BDBP12V1 (FANGA B+ BLOC P) showed a good acceptance level and provided a complete effectiveness (100.0%) against the *Mus musculus* population present across the trial site when used at the application rate of 100 g per bait stations		
BDBP12V1 (FANGA B+ BLOC P) 0.0012% Brodifacoum 2 year aged	Brown rat	Laboratory study Test protocol VPU/15/04 and method: Technical Notes for Guidance on Product	Acclimatization: 4 days in individual cage at room temperature. Intoxication phase: 4 days Standard Laboratory diet was removed and replaced by the Test Bait (A) and Reference (RM3 ground laboratory diet) (B) Each day, the hoppers were weighted,	The BDBP2V1 (FANGA B+ BLOC P) 2 years aged bait containing 12 ppm brodifacoum weathered in damp conditions (T° 30-35 °C, RH 80 %)	PRESCOTT C. V. *2013.BCD.SAG16*	*1*

5 days aged in damp condition		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	readjusted and its places were inverted. Losses were also weighted. Daily bait consumptions were measured and the respective consumptions of bait were determined in relation with the body weight of animals. All used Test Bait and Reference is discarded and fresh quantities of each diet are placed in clean pot. In placing the pots back in the cage, the positions of the rodenticide and the reference diet should be interchanged to avoid place preference. This procedure will be repeated every day during the choice period. Post-treatment phase: After day 4 the animals should be returned to the standard laboratory diet. Mortality was observed during 22 days every 24 hours.	was given to brown rats (5 males and 5 females) during 4 days The study has demonstrated: - A mean palatability equivalent to 0.20 - A total efficacy, with 100% of mortality between D3 to D5. In damp conditions		
BDBP12V1 (FANGA B+ BLOC P) 0.0012% Brodifacoum 21 months aged	House mouse (*Mus musculus*)	Field test EPPO PP 1/114(2)	The trial was set up in an agricultural habitat (cows breeding stable, fodder and equipment warehouse) in which mice infestation was signalled by the farmer - 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 mice population size index x 100] where:	The trial was set up in an agricultural habitat (cows breeding stable for horses, fodder and equipment warehouse) in which mice infestation was signalled by the farmer. The farm site was surveyed and a notable mice presence over the entire site was detected. The	Rovetto I. Study n°2019.BCD.SAG16	*1*

			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 2016-04-26 to 2016-05-19	analysis of the observed runways, footprints and faeces allowed these mice to be identified as belonging to *Mus musculus* 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 mice population size during a Pre-treatment *census* (monitoring of the daily consumption of unpoisoned *placebo* baits). On the same way it was calculated an index of the mice population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned *placebo* baits during the Post-treatment		

				phase). According to the results of the present study, BDBP12V1 (FANGA B+ BLOC P) showed a good acceptance level and provided a complete effectiveness (100.0%) against the *Mus musculus* population present across the trial site when used at the application rate of 40 g per bait station.		