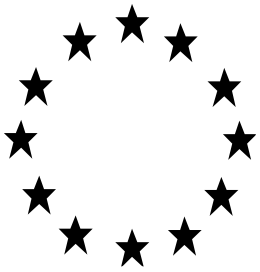
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL APPLICATION

(Submitted by the competent authority)



Brodifacoum Family – PT14

Product type 14

Brodifacoum

Case Number in R4BP: BC-NR064637-08

Competent Authority: EE CA

Date: 02 May 2022

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Changes history table

Application type	refMS/eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	UK, UK CA	-	31.01.2018	Initial assessment	-
NA-MIC	UK, UK CA	-	06.09.2018	Change of the family structure (from 2 meta SPCs to 4 meta SPCs	NA
NA-MAC	Estonia, EE CA	BC-NR064637-08	16.05.2022	Composition change – Paste bait Addition of the target organism – *Rattus rattus* Removal of 2 formulations/ 2 meta SPCs – blocks and pasta Shelf-life extension to 24 months for the grain and paste formulations	3.5/ 4.2.1.4/ All the info regarding blocks and pasta formulations have been removed
NA-RNL	Estonia, EE CA	BC-BH068921-43	In progress	*[Renewal of the authorisation]*	4.2.2

1 Conclusion

The Brodifacoum Family – PT14 consists of products containing the active substance brodifacoum. The products are grain and paste baits. The BPF is used for *indoor and outdoor use* by *professionals and non-professional users* for the control of *rats and mice.*

The BPF consists of 2 meta-SPCs. The structure of the BPF into meta-SPCs was based on formulation type.

General

Detailed information on the intended uses of the BPF as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the BPF and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals, and the environment are reported in sections 4 and 5 of the SPC.

A classification according to Regulation (EC) No 1272/2008[1] is necessary. Detailed information on classification and labelling is provided in section 2.9 of the PAR. The hazard and precautionary statements of the BPF according to Regulation (EC) No 1272/2008 are available in the SPC, in section 3 for each meta-SPC.

The BPF does not contain any non-active substances (so called "co-formulant(s)") which are considered as substances of concern.

The BPF contains the active substance Brodifacoum, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

The BPF contains Brodifacoum which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: Toxic for reproduction (R), Cat 1A; Persistent (P) or very Persistent (vP); Bioaccumulative (B) or very Bioaccumulative (vB); Toxic (T)

Therefore, a comparative assessment has been performed in accordance with Article 23(1) of Regulation (EU) No 528/2012 and following the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a – Final)[2]. The competent authority concluded that the criteria according to Article 23 (3) a) and b) of Regulation (EU) 528/2012 are not fulfilled. Therefore, the authorisation of the product family Brodifacoum Family – PT14 can be authorised for a period of 5 years in accordance with Article 23(6) of EU Regulation 528/2012.

Composition

The qualitative and quantitative information on the non-confidential composition of the BPF is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer(s) of the biocidal products is listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance(s) in the BPF are met. More information is available in sections 2.5 and 2.6 of the PAR. The manufacturer(s) of the active substance(s) are listed in section 1.5 of the

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

[2] The document is available in CIRCABC at https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3.

SPC.

Conclusions of the assessments for each area

The intended use(s) as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal products. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the concentration of the active substance, residues, relevant impurities and substances of concern is available. More information on the analytical methods for the active substance(s) is available in section 3.4 of the PAR.

Efficacy against target organisms

The BPF has been shown to be efficacious against *House mice and rats* for all intended uses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.6 of the PAR.

Since no substance of concern has been identified, the human health risk assessment is based on the active substance brodifacoum.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable acute or chronic risk to professional users, non-professional users and professional bystanders and non-professional bystanders/general public, if the directions for use, as specified in the SPC, are followed.

Dietary risk assessment

Considering the uses, food or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substance is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for animal health

Considering the uses, exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.8 of the PAR.

Since no substance of concern has been identified, the risk assessment for the environment is based on the active substance brodifacoum.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed.

Post-authorisation conditions

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Table 1.1 Post-authorisation conditions

Description	Due date
None	-

2 Information on the biocidal product family

2.1 Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

Product type(s)	*PT14*
Type(s) of formulation	*RB – Bait (ready for use) Meta SPC1; RB – Bait (ready for use) Meta SPC 2*

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the BPF

Use number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (by CA)[8]	Comment[9]
[1.1]	Grain - House mice and/or rats – Trained Professional users – indoor	PT14	House mice; Rats	Ready-to-use bait to be used in tamper-resistant bait stations; Covered and protected baiting points	Mice: Up to 50g of bait per baiting point Rats: Up to 200g of bait per baiting point	Trained professional	R	Human health, environment
[1.2]	Grain - House mice and/or rats – Trained professional users – outdoor around buildings						R	
[1.3]	Grain – Brown rats – Trained professional users – sewers		Brown rats	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water; Covered and protected baiting points	Up to 300g per manhole		R	
[1.4]	Grain - House mice – non-professional users (general public) – indoor	PT14	House mice	Ready-to-use bait to be used in tamper-resistant bait stations	Up to 50g	Non-Professional	R	Human health, environment
[1.5]	Grain - Rats – non-professional users (general public) – indoor		Rats		Up to 150g		R	
[1.6]	Grain - Rats – non-professional users (general public) – outdoor around buildings		Rats		Up to 150g		R	Human health, environment

Use number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (by CA)[8]	Comment[9]
[1.7]	Grain - House mice and/or rats – Professional users – indoor	PT14	House mice; Rats	Ready-to-use bait to be used in tamper-resistant bait stations	Mice: Up to 50g of bait per baiting point Rats: Up to 200g of bait per baiting point	Professional	R	Human health, environment
[1.8]	Grain - House mice and/or rats – Professional users – outdoor around buildings						R	Human health, environment
[2.1]	Paste - House mice and/or rats – Trained Professional users – indoor	PT14	House mice; Rats	Ready-to-use bait to be used in tamper-resistant bait stations; Covered and protected baiting points	Mice: Up to 50g of bait per baiting point Rats: Up to 200g of bait per baiting point	Trained professional	R	Human health, environment
[2.2]	Paste - House mice and/or rats – Trained professional users – outdoor around buildings						R	Human health, environment
[2.3]	Paste - House mice and/or rats – Professional users – indoor	PT14	House mice; Rats	Ready-to-use bait to be used in tamper-	Mice: Up to 50g of bait per baiting point Rats: Up to 200g of bait	Professional	R	Human health, environment

Use number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (by CA)[8]	Comment[9]
[2.4]	Paste - House mice and/or rats – Professional users – outdoor around buildings			resistant bait stations	per baiting point		R	Human health, environment

[1] Use number (as applied for) to be indicated together with the meta-SPC number, as in the SPC (e.g. 1.2, where "1" is the meta-SPC and "2" is the use number within the meta-SPC)
[2] Title of the specific use (as applied for), as indicated in the SPC
[3] Product type(s) of the use(s)
[4] Target organisms, group of organisms
[5] Application method for all meta-SPCs for the specific use
[6] Min-max. application rate of the product(s) for the specific use
[7] User categor(y/ies), e.g. general public, non-professional, professional, industrial
[8] eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

[9] If the use or meta-SPC is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

2.3 Similarity of the group of products for which the authorisation as a biocidal product family is sought

The application for authorisation as a BPF explicitly identified the maximum risks to human health, animal health, and the environment, and the minimum level of efficacy.

All the products applied for include the same active substance and are similar in composition. Information on the similarity of composition and the identified worst and best case composition are provided in the confidential annex.

Table 2.3 Overview regarding the similarity of the intended uses

Use number	Product type	Reference[1]	Use pattern[2]
[1.1] – [1.8]	*[PT14]*	#45	Rodenticides - Use as bait
[2.1] – [2.4]	*[PT14]*	#45	Rodenticides - Use as bait

[1, 2] As indicated in the Note for Guidance "Implementing the concept of biocidal product family" (CA-July19-Doc4.2-Final).

The agreed general criteria for deciding on whether the intended uses can be considered as similar were applied, according to the document CA-July19-Doc.4.2-Final entitled "Implementing the concept of biocidal product family".

In accordance with the agreed general criteria, all the intended uses are considered similar uses, in line with the document CG-34-2019-12 AP 15.1 Assessment of similarity in BPF.docx ("Section 2 – Similarity of uses"). The corresponding justification(s) provided by the applicant are considered acceptable.

All the intended uses as applied for by the applicant have been assessed. By considering only those uses appropriate for authorisation which bear a consistent set of instructions for use, RMMs etc. (e.g. same RMMs from best to worst case composition), it was ensured that all products of the BPF have a similar level of risk and efficacy.

2.4 Identity and composition

The identity and composition of the following product(s) within the BPF:
Brodifacoum Grain and Brodifacoum 25 Paste are

identical ☐
not identical ☒

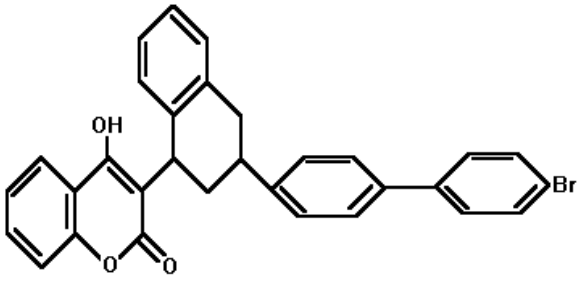
to the identity and composition of the product(s) evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation (EU) No 528/2012.

The qualitative and quantitative information on the non-confidential composition of the meta-SPC(s) and of the individual product(s) is detailed in sections 2.1 and 7 of the SPC, respectively. Information on the full composition is provided in the confidential annex.

2.5 Identity of the active substance(s)

Table 2.4 Identity of the active substance(s)

Main constituent(s)	
Common name	*Brodifacoum*
Chemical name	*3-[(1RS,3RS;1RS,3SR)-3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin*
EC number	259-980-5

CAS number	56073-10-0
Index number in Annex VI of CLP	607-172-00-1
Minimum purity / content	≥95.0 % w/w Pelgar: 99.2 % w/w Syngenta 95.0 % w/w
Structural formula	

2.6 Information on the source(s) of the active substance(s)

Is the source of Brodifacoum supplied by Pelgar International Limited the same as the one(s) evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☒ Yes
☐ No

Is the source of Brodifacoum supplied by Syngenta Crop Protection AG the same as the one(s) evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☒ Yes
☐ No

2.7 Candidate(s) for substitution

The following candidate for substitution has been identified:

- Brodifacoum

The following criteria for substitution are met:

- Toxic for reproduction (R), Cat 1A
- Persistent (P) or very Persistent (vP)
- Bioaccumulative (B) or very Bioaccumulative (vB)
- Toxic (T)

2.8 Assessment of the endocrine-disrupting properties of the biocidal product family

The BPF contains the active substance *brodifacoum* which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) No 2017/2100.

Based on the available information, it was not possible to conclude whether the non-active substances should be considered to have ED properties during the assessment of this NA-

MAC. More detailed information is available in the confidential annex.

2.9 Classification and labelling

Table 2.5 Classification and labelling of the BPF

[Meta SPC 1]	**Classification**	**Labelling**
Hazard Class and Category code	*STOT RE 2*	*STOT RE 2*
Hazard Pictograms	*GHS08*	GHS08
Signal word(s)	*Warning*	Warning
Hazard statements	H373 – May cause damage to organs (blood) through prolonged or repeated exposure.	H373 – May cause damage to organs (blood) through prolonged or repeated exposure.
Precautionary statements*	P260 – Do not breathe dust. P314 – Get medical advice/attention if you feel unwell. P501 – Dispose of contents and container in accordance with national regulations.	P260 – Do not breathe dust. P314 – Get medical advice/attention if you feel unwell. P501 – Dispose of contents and container in accordance with national regulations.
Supplemental hazard statements	-	
Notes	*None*	

*****P-statements that are excluded based on the risk assessment or the intended use of the product(s)[3], are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

[3] Section 3 of the CA note of Q&A concerning the content of some SPC sections. The document is available at https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b.

[Meta SPC 2]	**Classification**	**Labelling**
Hazard Class and Category code	STOT RE 2	*STOT RE 2*
Hazard Pictograms	GHS08	GHS08
Signal word(s)	Warning	Warning
Hazard statements	H373 – May cause damage to organs (blood) through prolonged or repeated exposure.	H373 – May cause damage to organs (blood) through prolonged or repeated exposure.
Precautionary statements*	P314 – Get medical advice/attention if you feel unwell. P501 - Dispose of contents and container in accordance with national regulations.	P314 – Get medical advice/attention if you feel unwell. P501 – Dispose of contents and container in accordance with national regulations.
Supplemental hazard statements	[EUH208 - Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.]	
Notes	*None*	

2.10 Letter of access

The Letters of Access to the active substance brodifacoum have been provided by the owners of the active substance dossiers - Pelgar International Limited and Syngenta Crop Protection AG. These Letters of Access have been submitted.

2.11 Data submitted in relation to product authorisation

Not relevant.

2.12 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product family

3.1 Packaging

No change.

3.2 Physical, chemical, and technical properties

Information on the choice of the worst case composition for physical, chemical, and technical properties (e.g. representative test product(s)) and the justification for why the chosen test product(s) are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

Brodifacoum family - PT14 is a family of ready for use bait formulations. None of these products were the representative formulation considered for BPR inclusion of the active substance.
The physical, chemical and storage stability data submitted to support the formulations are summarised in the following table.

The BPF consists of 2 meta-SPCs with varying compositions. Data have been provided on 2 products to support the respective meta-SPCs. Meta-SPC1 is supported by data on 'brodifacoum grain bait'. Meta-SPCs 2 is supported by data on 'brodifacoum paste'. These data provided are considered representative of each of the meta-SPCs.

Table 3.1 Physical, chemical, and technical properties

24 month storage stability studies were submitted to the existing data and the results can be found below.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)[4]	Results	Reference (new tests submitted with NA-MAC are highlighted in grey)
3.1.	Appearance at 20 °C and 101.3 kPa				
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual assessment	Brodifacoum Grain (0.0025%)	Solid, loose, whole grain bait.	Rentokil Initial 1927 plc, 2016, Physical and Chemical Properties of Biocidal Product
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual assessment	Brodifacoum 25 Paste (0.0025%)	Solid, paste bait.	Swetman, J, 2017, Study number: 261/13
3.1.2.	Colour at 20 °C and 101.3 kPa	Visual assessment	Brodifacoum Grain (0.0025%)	Blue	Rentokil Initial 1927 plc, 2016, Physical and Chemical Properties of Biocidal Product
3.1.2.	Colour at 20 °C and 101.3 kPa	Visual assessment	Brodifacoum 25 Paste (0.0025%)	Blue	Swetman, J, 2017, Study number: 261/13
3.1.3.	Odour at 20 °C and 101.3 kPa	Odour assessment	Brodifacoum Grain (0.0025%)	Odourless	Rentokil Initial 1927 plc, 2016, Physical and Chemical Properties of Biocidal Product
3.1.3.	Odour at 20 °C and 101.3 kPa	Odour assessment	Brodifacoum 25 Paste (0.0025%)	Odourless	
3.2.	Acidity, alkalinity, and pH value	-	-	The Brodifacoum Family – PT14 is composed by solid products thus a 1% aqueous solution, emulsion or dispersion cannot be made.	

[4] The reported content of the active substance - 0.0025% - corresponds to the pure content.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)[4]	Results	Reference (new tests submitted with NA-MAC are highlighted in grey)
				The pH, acidity or alkalinity of these products cannot therefore be measured.	
3.3.	Relative density / bulk density	OECD 109	Brodifacoum grain bait - Results for similar product 'Rodine rat and mouse killer', 0.005 % bromadiolone	Tap density = 0.68 g/mL	Keay, S., 2013 Study number 261/07
		OECD 109	Brodifacoum 25 Paste - Results for similar product 'Talon Soft', 0.005 % brodifacoum	Density = 1.14 g/mL	Swetman, S., 2017 Study number 261/12
3.4.1.1.	Storage stability test – **accelerated storage**	-	-	N/A – long term storage at ambient temperature has been provided.	
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	24 month storage trial at ambient temperature in accordance to procedure SOP: LM 033, Part 1, Issue 7 (issued 11/03/2013) and Issue 8 (issued 18/05/2017) – Test Method to Determine the Storage Stability Performance of Products in Packs and Containers.	Brodifacoum grain bait (0.0025%)	Pack integrity and appearance: Bait in clear plastic sachets within printed cardboard box noted at initial inspection. There was no noted visible change to the packaging at the 24 month inspection interval. Product appearance: Blue grain bait was noted at initial inspection. No visible	Keay S., 2018, Study number 244/100

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)[4]	Results	Reference (new tests submitted with NA-MAC are highlighted in grey)
		Analysis of the active ingredient was carried out according to procedure SOP:AM 119, Issue 5 (issued 16/03/2016 – Determination of Brodifacoum in Bait Blocks and Grain Baits by Reverse Phase Liquid Chromatography.		change recorded at the 24 month inspection interval. There was a small change in weight of the pack upon storage of Brodifacoum Grain Bait at ambient temperatures during the trial period. The active ingredient analysis of Brodifacoum Grain Bait shows an increase in the level of brodifacoum concentration in the product upon storage. The change from initial content at 24 months was 4.3% increase. This increase is within the allowable variance of ≤10%, as specified in the Guidance on the BPR: Volume I, Part A, Chapter III Requirements for Biocidal Products, Version 1.1 November 2014, and it is recognised that this should not adversely effect the efficacy and risk assessment of the product.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)[4]	Results	Reference (new tests submitted with NA-MAC are highlighted in grey)
3.4.1.2.	**Storage stability test – long-term storage at ambient temperature**	24 month storage trial at ambient temperature in accordance to procedure SOP:AM No. 101, Part 47A, Issue 1 (issued 20/06/2019) – Test Method to Determine the Storage Stability Performance of Products in Packs or Containers. Analysis of the active ingredient was carried out according to procedure SOP:AM 171, Issue 9 (issued 03/06/2019) – Determination of Brodifacoum in Brodifacoum Paste, Pasta Bait and Fat Based Brodifacoum Blocks by Reverse Phase Liquid Chromatography and Issue 10 (issued 08/10/2019) – Determination of Brodifacoum in Brodifacoum Paste, Pasta/Soft Bait and Fat Based Brodifacoum Blocks	Brodifacoum 25 Paste (0.0025%) with BIT	Pack integrity and appearance: Intact white high density polyethylene (HDPE) cylinder noted at initial inspection (picture 1A). There was no noted observed change to the white plastic tube at the 12 month, 18 month and 24 month inspection intervals. Product appearance: Blue paste of uniform nature noted at initial inspection. There was no noted observed change to the product at the 12 month, 18 month and 24 month inspection intervals. Pack weight: There was a small change in weight of the pack upon storage of Brodifacoum 25 Paste with BIT at ambient temperatures during the trial period. Active ingredient content: The active ingredient analysis of Brodifacoum 25 Paste with BIT shows a decrease in the level of total brodifacoum concentration in the product upon storage	Anthati P, Keay S, 2021, Study number: 244/116

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)[4]	Results	Reference (new tests submitted with NA-MAC are highlighted in grey)
		by Reverse Phase Liquid Chromatography.		over the 24 month period. The change from initial content at 24 months was 8.00% decrease. The change in brodifacoum concentration, for the batch number tested, is within the allowable variance of ≤10%, as specified in the Guidance on the BPR: Volume I, Part A, Chapter III Requirements for Biocidal Products, Version 1.1 November 2014 – Section 3.4.2 and it is recognised that this should not adversely effect the efficacy and risk assessment of the product. The temperature and relative humidity of the storage stability facility throughout the trial is summarised in Appendix 1 of the study report.	
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	-	-	-	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)[4]	Results	Reference (new tests submitted with NA-MAC are highlighted in grey)
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	-	-	Packaging for the biocidal product families are opaque therefore the effects of light will be minimal.	
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	-	
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	-	
3.5.1.	Wettability *[indicate the concentration tested]*	-	-	-	
3.5.2.	Suspensibility, spontaneity, and dispersion stability *[indicate the concentration tested]*	-	-	-	
3.5.3.	Wet sieve analysis and dry sieve test *[indicate the concentration tested]*	-	-	-	
3.5.4.	Emulsifiability, re-emulsifiability, and emulsion stability *[indicate the concentration tested]*	-	-	-	
3.5.5.	Disintegration time	-	-	-	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)[4]	Results	Reference (new tests submitted with NA-MAC are highlighted in grey)
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability *[the particle size distribution of droplets (MMAD) should be reported for RTU products if sprayed.]*	-	-	-	
3.5.7.	Persistent foaming *[indicate the concentration tested]*	-	-	-	
3.5.8.	Flowability/pourability/dustability	-	-	-	
3.5.9.	Burning rate — smoke generators	-	-	-	
3.5.10.	Burning completeness — smoke generators	-	-	-	
3.5.11.	Composition of smoke — smoke generators	-	-	-	
3.5.12.	Spraying pattern — aerosols / spray	-	-	-	
3.6.1.	Physical compatibility	-	-	Brodifacoum family – PT14 products are ready to-use. They are not designed to be used in conjunction with any other products or active substances. They are not expected to be incompatible with any other products or active substances. Hence, no data on the physical and chemical compatibility of Brodifacoum family –	
3.6.2.	Chemical compatibility				

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)[4]	Results	Reference (new tests submitted with NA-MAC are highlighted in grey)
				PT14 products with other products, chemicals or active ingredients, has been submitted.	
3.7.	Degree of dissolution and dilution stability *(indicate the concentration tested)*	-	-	-	
3.8.	Surface tension *[indicate the conditions of the test and the concentration tested]*	-	-	Surface tension is defined as the force acting on the surface of a liquid, tending to minimise the area of the surface. Brodifacoum Family – PT14 is composed by solid products therefore it is neither informative nor possible to measure the surface tension.	
3.9.	Viscosity *[indicate the shear rate and the temperature tested]*	-	-	Viscosity is a measure of the flowability of a liquid. Brodifacoum Family – PT14 is only composed by solid products. Therefore, it is neither informative nor possible to measure the viscosity.	

Table 3.2 Conclusion on physical, chemical and technical properties

Conclusion on physical, chemical, and technical properties
[Meta-SPC1]: The representative product Brodifacoum Grain of meta-SPC 1 is a ready-to use grain bait. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. *[Meta-SPC2]:* The representative product Brodifacoum 25 Paste of meta-SPC 2 is a ready-to use paste bait. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. **Implications for labelling for meta-SPC 1 and 2:** *None*

3.3 Physical hazards and respective characteristics

Information on the choice of the worst case composition for physical hazards and respective characteristics (e.g. representative test product(s)) and the justification for why the chosen test product(s) are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

Neither new data were provided, nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

Table 3.3 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	Waiver	-	None of the components present in Brodifacoum Family – PT14 products are classified as explosive and all are stable under normal conditions.
4.2.	Flammable gases	Not applicable	-	Not applicable – The formulations included in Brodifacoum family are solid
4.3.	Flammable aerosols	Not applicable	-	Not applicable – The formulations included in Brodifacoum family are solid
4.4.	Oxidising gases	Not applicable	-	Not applicable – The formulations included in Brodifacoum family are solid
4.5.	Gases under pressure	Not applicable	-	Not applicable – The formulations included in Brodifacoum family are solid
4.6.	Flammable liquids	Not applicable	-	Not applicable – The formulations included in Brodifacoum family are solid
4.7.	Flammable solids	Waiver	-	None of the components of Brodifacoum Family Products are classified as flammable and all are stable under normal conditions.
4.8.	Self-reactive substances and mixtures	Waiver	-	None of the components of Brodifacoum Family Products are classified as Self-reactive and all are stable under normal conditions.
4.9.	Pyrophoric liquids	Not applicable	-	Not applicable – The formulations included in Brodifacoum family are solid

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.10.	Pyrophoric solids	Waiver	-	None of the components of Brodifacoum Family Products are classified as Pyrophoric and all are stable under normal conditions.
4.11.	Self-heating substances and mixtures	Waiver	-	None of the components of Brodifacoum Family Products have self-heating properties.
4.12.	Substances and mixtures which in contact with water emit flammable gases	Not applicable	-	None of the components of Brodifacoum Family Products emit flammable gases when in contact with water
4.13.	Oxidising liquids	Not applicable	-	Not applicable – The formulations included in Brodifacoum family are solid
4.14.	Oxidising solids	Waiver	-	None of the components of Brodifacoum Family products are classified as oxidising and all are stable under normal conditions.
4.15.	Organic peroxides	Not applicable	-	Brodifacoum Family products do not contain hydrogen peroxide or its derivatives
4.16.	Corrosive to metals	Not applicable	-	None of the components of Brodifacoum Family products are classified as corrosive to metals
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Not applicable	-	Not applicable – The formulations included in Brodifacoum family are solid
4.17.2.	Relative self-ignition temperature for solids	Not applicable	-	None of the products in the Brodifacoum family showed no evidence of flammability in use or instability, therefore it is not considered that these products represent a spontaneous ignition hazard.
4.17.3.	Dust explosion hazard	Not applicable	-	Grain bait - This product is a ready-to-use grain bait, but is not granular or a powder form, or dusty. Paste bait – Not applicable

Table 3.4 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
[meta-SPC1]: Based on the assessment of the representative product Brodifacoum Grain, meta-SPC 1 is not classified for the physical hazards. [meta-SPC2]: Based on the assessment of the representative product Brodifacoum 25 Paste, meta-SPC 2 is not classified for the physical hazards.

3.4 Methods for detection and identification

Information on the choice of the worst case composition for methods for detection and identification (e.g. representative test product(s)) and the justification for why the chosen test product(s) are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

Table 3.5 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
SPC 1 - Brodifacoum Grain Principle of the method *[*Analytical Method SOP:AM 119, Issue 5 – Determination of Brodifacoum in Bait Blocks and Grain Bait by Reverse Phase Liquid Chromatography ; Analytical Method (SOP:AM) No. 101, Part 2, Issue 11 "Method Validation"*]:* The grain samples are ground and mixed well then 25 g of sample weighed into a thimble. The sample is soaked overnight in 50 mL methanol and 30 mL acetone. The samples are then extracted twice using Soxtec apparatus and diluted to a sample volume of 100 mL with methanol. The resulting solution is filtered and analysed by Reverse Liquid Chromatography with an ultraviolet detector; LC column: 4.6 mm x 250 mm reverse phase. The brodifacoum sample concentration is approximately 6.25]g/ml.											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Brodifacoum	1.01 – 20.16]g/mL Equivalent to 15 - 320 % nominal content. n = 7 R^2 = >0.9999 Linearity equation: y = 0,95048x + 0,13342	Spectra of the blank, standard solutions and test solution were provided showing no evidence of interference. The retention time of brodifacoum is ca. 11.7 min.	0.0199 % w/w 0.00250 % w/w 0.00299 % w/w	6	Recovery range of 80 to 120%. The acceptable range of the method is set to ±20% of the declared concentration.	98.24 % (6) %RSD = 3.27 % 103.09 % (6) %RSD = 5.31 % 109.16 % (6) %RSD = 2.85 %	% RSD = 4.33 (12) for a mean content of 0.002311 % w/w Acceptable Horwitz = 6.68 %	Sample mean ($\overline{x}$) % m/m: 0.002311	12	LOQ = 0.000747 % m/m	Swetman, J., 2016, project 302/14

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
SPC 2 – Brodifacoum 25 Paste Principle of the method [Analytical method SOP:AM 171, issue 10 – Determination of Brodifacoum in Brodifacoum Paste, Pasta/Soft bait and Fat Based brodifacoum blocks by Reverse Phase Liquid Chromatography]: the brodifacoum is extracted from the fat based bait with a mixture of acetonitrile, water and acetic acid. Hexane is also added to remove the fat into a separate phase. The resulting extract is filtered and analysed by Reverse Phase Liquid Chromatography with an Ultraviolet detector.]											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit (y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Brodifacoum	1.00 to 19.91µg/ml n = 5 R^2 = >0.9999 Linearity equation: y = 0,872123x - 0,001459	Spectra of the blank, standard solutions and test solution were provided showing no evidence of interference.	0.002021 %w/w; 0.002508 %w/w; 0.003031 %w/w	6	Recovery range of 80 to 120%. The acceptable range of the method is set to ±20% of the declared concentration.	83.13 % (6) - %RSD =0.46 % 82.58 % (6) - %RSD =0.43 % 82.65 % (6) - %RSD =0.85 %	% RSD – 1.25% (12) for a mean content of 0.002083% w/w	Sample mean ($\overline{X}$) % m/m: 0.002083	12	LOQ, cis-brodifacoum = 0.08 µg/ml LOD, trans-brodifacoum = 0.10 µg/ml	Keay S., Project 302/30

Table 3.6 Analytical methods for soil

Analytical methods for soil									
Analyte (type of analyte e.g. active	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration	Number of		

substance) **Analytical method**							tested	replicates		
-	-	-	-	-	-	-	-	-	-	-

Table 3.7 Analytical methods for air

Analytical methods for air										
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		
-	-	-	-	-	-	-	-	-	-	-

Table 3.8 Analytical methods for water

Analytical methods for water										
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		
-	-	-	-	-	-	-	-	-	-	-

Table 3.9 Analytical methods for animal and human body fluids and tissues

Analytical methods for animal and human body fluids and tissues										
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		
-	-	-	-	-	-	-	-	-	-	-

Table 3.10 Analytical methods for monitoring of active substances and residues in food and feeding stuff

Analytical methods for monitoring of active substances and residues in food and feeding stuff										
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		
-	-	-	-	-	-	-	-	-	-	-

Table 3.11 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
An Analytical method *[Analytical Method SOP:AM 119, Issue 5 – Determination of Brodifacoum in Bait Blocks and Grain Bait by Reverse Phase Liquid Chromatography ; Analytical Method (SOP:AM) No. 101, Part 2, Issue 11 "Method Validation"; Analytical method SOP:AM 171, issue 10 – Determination of Brodifacoum in Brodifacoum Paste, Pasta/Soft bait and Fat Based brodifacoum blocks by Reverse Phase Liquid Chromatography]* for the determination of Brodifacoum is available. Specificity, linearity, accuracy and precision were checked and found acceptable. Methods for the detection of brodifacoum in soil, air, water, and animal and human body fluids and tissues have not been provided by the applicant since these points are covered by the data set for the active substance. Therefore, concerning product authorisation no further data is required. The products are not intended to be used on surface in contact with food/feed of plant and animal origin; therefore, analytical method for the determination of active substance in food/feed of plant and animal origin is not required. As no MRL were fixed, no analytical method for the determination of active substance in food/feed of plant and animal origin is required.

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

The Brodifacoum product family are rodenticides (product type 14) to be used against Brown rats (*Rattus norvegicus*), Black rats (*Rattus rattus*) and House mice (*Mus musculus*) by professional and non-professional users.

The product family includes grain and paste baits containing 0.0025% brodifacoum. The products are to be used in tamper-resistant bait stations and/or be applied in suitable covered and protected bait points.

The grain product is intended to be used in and around buildings and in sewers; and the paste product is intended to be used in and around buildings.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

Brodifacoum is a second-generation anticoagulant which prevents blood clotting in the target organisms by inhibiting the regeneration of the active form of vitamin K1. For more details see Document IIIA Section 5. Please refer to the Letter of Access for Brodifacoum.

Clinical signs are progressive and occur within 18 hours after ingestion of a toxic dose, ultimately leading to death from 3 to 10 days later. Effects are reversible by administration of the antidote vitamin K1 which stimulates the regeneration of the clotting factors.

3.5.3 Efficacy data

Table 3.12 Efficacy data

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
PT14, Use 1.1 and 1.2 – Rats- Indoor and outdoor use (around buildings only)	Brodifacoum Grain	5 x Male Wistar Rats 5 x Female Wistar Rats	Palatability Choice Test 4 days of baiting	75.8% palatability. 100% mortality in 17 days.	R Shand, 2015, Project report number 2015/246/64	*6.7.1/Bioassay of 25ppm Brodifacoum Paste and grain vs.rats@21°C*
		Wistar Rats	Palatability Choice Test 4 days of baiting	77.2% palatability. 100% mortality in 13 days.	*R Shand, 2016, project report number 2016/246/66*	6.7.1/ Bioassay of 25ppm Brodifacoum Grain vs Rats & Mice - Initial Storage Stability Trial

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
PT14, Use 1.1 and 1.2 – Rats-Indoor and outdoor use (around buildings only)	*Brodifacoum Grain*	Wistar Rats	Palatability Choice Test with aged bait after 24 months Rats placed into pen and acclimatised for 72hrs. Bait offered for 4 days with alternative lab diet also available. Observations made twice a day for a maximum period of 21 days	100% mortality in 10 days; palatability: 77.7%	R Shand, 2018, Project Report Number 2018/246/74	6.7.21/ Bioassay of 25ppm Brodifacoum Grain (24 month shelf life) vs TO mice & Wistar rats
		Wild Rat population *Rattus norvegicus*	Field Trial, Hythe, England. *Pre-treatment census non-toxic bait take measured for 4 days.* *Treatment period consisted of 26 days.* *Post-treatment census non-toxic bait take measured for 4 days.* *Footprints within sand boxes were not viable as a census measurement.* *The sand clumped too readily and dried out.*	*98.5% reduction in census bait take.*	*C Moore, 2017,* *Technical Report 2017/BD-02e*	*6.7.14/ Rodenticide Efficacy Field Trial: Brodifacoum loose grain (0.0025% brodifacoum) against Brown rats (Rattus norvegicus) at M20 Motorway Services, Stop 24 Services, Stanford Intersection, J11, Hythe, CT21 4BL*

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
PT14, Use 1.1 and 1.2 – Rats - Indoor and outdoor use *(around buildings only)*	Brodifacoum Grain	*Wild Rat population* *Rattus norvegicus*	*Field Trial, The 'Compound', Atherstone, England* *Pre-treatment census non-toxic bait take measured for 6 days.* *Treatment period consisted of 36 days.* *Post-treatment census non-toxic bait take measured for 6 days.* *Footprints within sand boxes were not viable as a census measurement.* *The sand clumped too readily and dried out.*	*100% reduction in census bait take.*	*C Moore, 2017,* *Technical Report 2017/BD-02d*	*6.7.15/ Rodenticide Efficacy Field Trial: Brodifacoum loose grain (0.0025% brodifacoum) against Brown Rat (Rattus norvegicus) at Twycross Zoo (Burton Rd, Atherstone, CV9 3PX) Field Trial Site B. 'The Compound'*
		Wild Rat population *Rattus norvegicus*	Field Trial, 'The Farm', Atherstone, England Pre-treatment census non-toxic bait take measured for 6 days. Treatment period consisted of 36 days. Post-treatment census non-toxic bait take measured for 6 days. Footprints within sand boxes were not viable as a census measurement. The sand clumped too readily and dried out.	100% reduction in census bait take.	C Moore, 2017, Technical Report 2017/BD-02c	*6.7.13/* Rodenticide Efficacy Field Trial: Brodifacoum Grain (0.0025% brodifacoum) against Brown Rat (*Rattus norvegicus*) at Twycross Zoo (Burton Rd, Atherstone, CV9 3PX) Field Trial Site A.

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
						'The Farm'.
PT14, Use 1.1 and 1.2 – Rats - Indoor and outdoor use *(around buildings only)*	Brodifacoum Grain	Black rats*, Rattus rattus*	Field trial, Rhone, France Pre-treatment census non-toxic bait take measured for 15 days. Treatment period consisted of 13 days. Post-treatment census non-toxic bait take measured for 4 days.	100% reduction in census bait take.	A Guicherd, 2020, Study No 20RENRrF003	*6.7.17/ Evaluation of the Efficacy of the bait 'Brodifacoum Grain bait' for the control of Black rat infestation in and around buildings. One field trial: Rhone, France, 2020.*
			Field trial, Rhone, France Pre-treatment census non-toxic bait take measured for 10 days. Treatment period consisted of 14 days. Post-treatment census non-toxic bait take measured for 4 days.	100% reduction in census bait take.	A Guicherd, 2020, Study No 20RENRrF001	*6.7.16/ Evaluation of the Efficacy of the bait 'Brodifacoum Grain bait' for the control of Black rat infestation in and around buildings. One field trial: Rhone, France, 2020*

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
PT14, Use 1.1 and 1.2 – Rats - Indoor and outdoor use *(around buildings only)*	Brodifacoum Grain	Black rats*, Rattus rattus*	Palatability Choice Test with aged bait after 24 months 4 days of baiting	100% of mortality between D6 and D8 for males and females; A mean bait palatability equivalent to 72.8%	A Guicherd, 2021, Study No 21RENRrLab001	*6.7.23/ Rodenticide Palatability and Efficacy Study of the 0.0025% w/w Brodifacoum Grain Bait in Black rat (Rattus rattus)*
PT14, Use 1.1 and 1.2 – Mice - Indoor and outdoor use *(around buildings only)*	Brodifacoum Grain	5 x Male MF1 Mice 5 x Female MF1 Mice	Palatability Choice Test 4 days of baiting	85.3% palatability. 100% mortality in 11 days.	R Shand, 2015, Project report number 2015/246/65	*6.7.1//Bioassay of 25ppm Brodifacoum Paste and grain vs.mice@21°C*
		MF-1 Mice	Palatability Choice Test 4 days of baiting	60.2% palatability. 100% mortality in 8 days.	*R Shand, 2016, project report number 2016/246/66*	6.7.1/ Bioassay of 25ppm Brodifacoum Grain vs Rats & Mice - Initial Storage Stability Trial
		10 Wild Oaklease Mice	Semi-field Trial Mice placed into pen and acclimatised for 72hrs. Bait offered for 4 days with alternative lab diet also available. Observations made twice a day for a maximum period of 21 days.	23.2% palatability. 100% mortality in 14 days.	*R Shand, 2017, Project report number 2017/246/71*	6.7.2/ Semi-field trial of 25ppm Brodifacoum Grain vs wild Oaklease mice

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
PT14, Use 1.1 and 1.2 – Mice - Indoor and outdoor use *(around buildings only)*	Brodifacoum Grain	Wild Mouse population *Mus domesticus*	Field trial, 'Gibbon Forest', Atherstone, England. Pre-treatment census non-toxic bait take measured for 6 days. Treatment period consisted of 36 days. Post-treatment census non-toxic bait take measured for 6 days. Footprints within sand boxes were not viable as a census measurement. The sand clumped too readily and dried out.	89.8% reduction in census bait take.	C Moore, 2017, Technical Report 2017/BD-02b	6.7.12/ Rodenticide Efficacy Field Trial: Brodifacoum Loose Grain (0.0025% brodifacoum) against House Mice (Mus domesticus) at Twycross Zoo (Burton Rd, Atherstone, CV9 3PX) Field Trial Site B. Gibbon Forest

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
PT14, Use 1.1 and 1.2 – Mice - Indoor and outdoor use (around buildings only)	Brodifacoum Grain	Wild Mouse population Mus domesticus	Field Trial, Orpington, England. Pre-treatment census non-toxic bait take measured for 3 days. Treatment period consisted of 11 days. Post-treatment census non-toxic bait take measured for 4 days. Footprints within sand boxes were not viable as a census measurement. The sand clumped too readily and dried out.	93% reduction in census bait take.	C Moore, 2017, Technical Report 2017/BD-02a	6.7.11/ Rodenticide Efficacy Field Trial: Brodifacoum Grain (0.0025% Brodifacoum) against House mice (Mus domesticus) at Homebase Orpington, Sevenoaks Way Industrial Estate, Main Road, St Paul's Cray Orpington, BR5 3UH
		TO mice	Palatability Choice Test with aged bait after 24 months Mice placed into pen and acclimatised for 72hrs. Bait offered for 4 days with alternative lab diet also available. Observations made twice a day for a maximum period of 21 days	100% mortality in 6 days; palatability: 34.2%	R Shand, 2018, Project Report Number 2018/246/74	6.7.21/ Bioassay of 25ppm Brodifacoum Grain (24 month shelf life) vs TO mice & Wistar rats

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
PT14, Use 1.3 – Brown rats - Sewers	Brodifacoum Grain	Brown Rats	Palatability Choice Test Grain samples placed into container, then placed into plant propagator 35°c for 5 days.	63.1% palatability.	R Shand, 2017	6.7.5/ Damp conditions palatability trial vs Rats and Mice
		Oaklease Wild Mice		85.1% palatability.		
PT14, Use 2.1 and 2.2 – Rats - Indoor and outdoor use *(around buildings only)*	Brodifacoum Paste	5 x Male Wistar Rats 5 x Female Wistar Rats	Palatability Choice Test 4 days of baiting	48.7% palatability 100% mortality in 18 days.	R Shand, 2015, Project report number 2015/246/64	6.7.3/Bioassay of 25ppm Brodifacoum Paste and grain vs.rats@21°C
		Wild Rat Population, *Rattus norvegicus*	Field Trial, Pukekohe, Auckland, New Zealand Pre-treatment census tracking pads and non-toxic bait take measured for 9 days. Treatment period consisted of 23 days. Post-treatment census tracking pads and nontoxic bait take measured for 9 days.	94.5% reduction in census bait take. 99.1% reduction in the tracking card scores.	L Shapiro, 2017, reference A16272PN1	*6.7.7/* Rentokil brodifacoum paste bait efficacy field trial on Norway rats

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
PT14, Use 2.1 and 2.2 – Rats - Indoor and outdoor use *(around buildings only)*	Brodifacoum Paste	Wild Rat Population, *Rattus norvegicus*	Field Trial, Rochester, England. Pre-treatment census non-toxic bait take measured for 4 days. Treatment period consisted of 16 days. Post-treatment census non-toxic bait take measured for 4 days.	97% reduction in census bait take.	C Moore, 2017, Technical Report 2017/BD-03a	*6.7.8/* Rodenticide Efficacy Field Trial: Brodifacoum paste formulation (0.0025% brodifacoum) against Brown Rat (*Rattus norvegicus*) at Chiquitos - Medway Valley Leisure Park (Chariot Way, Rochester, ME2 2FF)
			Field Trial, Mauku, Auckland, New Zealand Pre-treatment census tracking pads and non-toxic bait take measured for 7 days. Treatment period consisted of 23 days. Post-treatment census tracking pads and non-toxic bait take measured for 9 days.	92.0% reduction in census bait take. 90.9% reduction in the tracking card scores.	H Blackie,2017, Reference A16272PN2	*6.7.6/* Rentokil brodifacoum paste bait efficacy field trial on Norway rats
	Brodifacoum Paste with BIT	*Wistar rats*	Palatability Choice Test Rats placed into pen and acclimatised for 72hrs. Bait offered for 4 days with alternative lab diet also available. Observations made twice a day for a maximum period of 21 days	53.5% palatability; 100% mortality in 19 days	R Shand, 2019, Project report number 2019/246/78	*6.7.20/ Bioassay of 25ppm Brodifacoum Paste (Initial Shelf life) vs TO mice & Wistar rats*

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
PT14, Use 2.1 and 2.2 – Rats - Indoor and outdoor use *(around buildings only)*	Brodifacoum Paste with BIT	Black rats, *Rattus rattus*	Field trial, Isere, France Pre-treatment census non-toxic bait take measured for 16 days. Treatment period consisted of 18 days. Post-treatment census non-toxic bait take measured for 4 days.	100% reduction in census bait take.	A.Guicherd,2019, Report no 19RENRrF001	6.7.22/ Evaluation of the Efficacy of Paste bait for the control of the Black rat infestation in and around agricultural buildings. One field trial: Isere, France, 2019
			Field trial, Rhone, France Pre-treatment census non-toxic bait take measured for 20 days. Treatment period consisted of 19 days. Post-treatment census non-toxic bait take measured for 4 days.	100% reduction in census bait take.	A.Guicherd,2020, Study Report 20RENRrF002	6.7.18/ Evaluation of the Efficacy of the bait "Brodifacoum 25 Paste" for the control of black rat infestations in and around buildings, One field trial Rhone, France, 2020

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
PT14, Use 2.1 and 2.2 – Rats - Indoor and outdoor use *(around buildings only)*	Brodifacoum Paste with BIT	Black rats, *Rattus rattus*	Palatability Choice Test 4 days of baiting	A mean bait palatability equivalent to 65.6%; 100% mortality between D4 and D8.	A.Guicherd,2020, Study number 20RENRrLab001	6.7.19/ Rodenticide palatability and efficacy study of the Brodifacoum 25 pmm Paste in Black rat (*Rattus rattus*)
PT14, Use 2.1 and 2.2 – Mice - Indoor and outdoor use *(around buildings only)*	Brodifacoum Paste	5 x Male MF1 Mice 5 x Female MF1 Mice	Palatability Choice Test 4 days of baiting	44.1% palatability. 100% mortality in 5 days.	R Shand, 2015, Project report number 2015/246/65	*6.7.3//Bioassay of 25ppm Brodifacoum Paste and grain vs.mice@21°C*
		10 Wild Oaklease Mice	Semi field trial Mice placed into pen and acclimatised for 72hrs. Bait offered for 4 days with alternative lab diet also available. Observations made twice a day for a maximum period of 21 days.	46.55% palatability. 100% mortality in 6 days.	R Shand, 2017, Project report number 2017/246/72	*6.7.4/ Semi-field trial of 25ppm Brodifacoum Paste vs Wild Oaklease mice – Trial 1*
		Wild Mice Population *Mus domesticus*	Field Trial, Drury, Auckland, New Zealand. Pre-treatment census tracking pads and nontoxic bait take measured for 9 days. Treatment period consisted of 23 days. Post-treatment census tracking pads and nontoxic bait take measured for 9 days.	92.4% reduction in census bait take. 94.8% reduction in the tracking card scores.	L Shapiro, 2017, Reference number A16272PM1	*6.7.9/* Rentokil brodifacoum paste bait efficacy field trial on mice

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference** (new tests submitted with NA-MAC are highlighted in grey)	**Number in IUCLID section 6.7/Test report title**
PT14, Use 2.1 and 2.2 – Mice - Indoor and outdoor use (around buildings only)	Brodifacoum Paste	Wild Mice Population *Mus domesticus*	Field Trial, Pukekohe, Auckland, New Zealand. Pre-treatment census tracking pads and nontoxic bait take measured for 9 days. Treatment period consisted of 23 days. Post-treatment census tracking pads and nontoxic bait take measured for 9 days	88.2% reduction in census bait take. 93.9% reduction in the tracking card scores	L Shapiro, 2017, Reference number A16272PM2	*6.7.10/* Rentokil brodifacoum paste bait efficacy field trial on mice
	Brodifacoum Paste with BIT	*TO mice*	Palatability Choice Test Mice placed into pen and acclimatised for 72hrs. Bait offered for 4 days with alternative lab diet also available. Observations made twice a day for a maximum period of 21 days	40.8%. palatability; 100% mortality in 4 days	R Shand, 2019, Project report number 2019/246/78	*6.7.20/ Bioassay of 25ppm Brodifacoum Paste (Initial Shelf life) vs TO mice & Wistar rats*

3.5.4 Efficacy assessment

Information on the choice of the worst case composition for efficacy (e.g. representative test product(s) and expert judgement/bridging studies where applicable) and the justification for why the chosen test product(s) are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

This Section has been updated since the 1st authorisation:
New efficacy data on Black rats (*Rattus rattus*) has been provided to support the general claim "against rats".
A Palatability choice test was carried out for the paste formulation (with a preservative) to confirm that the formulation change did not affect any data previously submitted.
The efficacy and palatability data of the simulated-use choice tests with House mice and Brown rats (R Shand, 2015, Project report number 2015/246/65; R Shand, 2015, Project report number 2015/246/64; R Shand, 2019, Project report number 2019/246/78) are performed under very similar test conditions (experimental design, alternative food source). Therefore, they are suitable to show equal palatability and efficacy of the previous and the new formulation. By the whole data package, including the field tests with the product with the previous formulation, efficacy against House mice and Brown rats has been proven.

We have accepted the waiving of the field trials for House mice and Brown rats with the paste product with the new formulation. The waiving is supported by the applicant with the justification as given below.
Based on the efficacy and palatability data (R Shand, 2015, Project report number 2015/246/65; R Shand, 2015, Project report number 2015/246/64; R Shand, 2019, Project report number 2019/246/78) with House mice and Brown rats and on the similarity between the formulations, we can conclude the following:
- All the existing efficacy data for the former composition of the Paste applies to the new formulation.
- No field trials, for House mice and Brown rats, have been carried out using the new formulation, as no difference in field conditions is expected.

Efficacy Data against *R. norvegicus*:

Meta-SPC 1: Grain Bait

Two palatability studies using grain bait against *R. norvegicus* have been submitted. These studies show 77.2% and 75.8% palatability, 100% mortality was observed at 13 and 17 days respectively.

A wet aged bait palatability study has been submitted to support the use in sewers against Brown rats. The study uses a comparable bait type and shows 63.10% palatability against *R. norvegicus*.

Three field trials have been submitted in support of the grain product against rats. These field trials show 98.5%, 100% and 100% reduction from pre-census to post-census bait take after treatment against *R. norvegicus*.

As this formulation does not contain a preservative, a palatability study using aged grain bait against *R. norvegicus* has been submitted. This study shows a 77.7% palatability and 100% mortality was observed in 10 days.

Conclusions: The data provided was sufficient to support the claim against Brown rats (*R. norvegicus*) at the first authorisation and we believe it still applies as no changes have been made to the product formulation. Data on aged bait has been provided to extend the product shelf life to 2 years.

Meta-SPC 2: Paste Bait

A palatability study that demonstrates 48.70% palatability of the paste bait against *R. norvegicus* with 100% mortality in 18 days has been submitted.

Three field studies have been submitted to support the use of the paste bait against rats. The first study shows a 94.5% reduction from pre to post census bait take and 99.1% reduction in tracking score. The second study shows a 97% reduction in bait take and the third study shows a 92% reduction in bait take and a 90.9% reduction in tracking score.

Due to a formulation change, a new palatability study has been provided to demonstrate that the changes on the formulation do not affect the product efficacy. The new palatability study shows a 53.5% palatability of the paste bait against *R. norvegicus* with 100% mortality in 19 days. Based on this data, we can conclude that all the existing efficacy data applies to the new formulation.

Conclusions: The data provided was sufficient to support the claim against Brown rats (*R. norvegicus*) at the first authorisation. Due to the formulation change, a new palatability study was carried out which demonstrates that the new formulation is sufficiently similar to the previous one. Therefore, all the efficacy data generated for the paste product is still valid and acceptable.

Efficacy Data against *R. rattus*:

Meta-SPC 1: Grain Bait

Two field trials have been submitted in support of the grain product against rats. These field trials show 100% reduction from pre-census to post-census bait take after treatment against *R. rattus*.

One palatability study using aged grain bait against *R. rattus* has been submitted as this formulation does not contain a preservative. This study shows a mean bait palatability equivalent to 72.8% and 100% of mortality between D6 and D8 for males and females.

Conclusions: We believe that this data is acceptable and sufficient to support the claim against Black rats (*R. rattus*). This data has been generated to support the general claim "against rats".
Data on aged bait has been provided to extend the product shelf life to 2 years.

Meta-SPC 2: Paste Bait

Two field trials have been submitted to support the use of the paste product against rats. These field trials show a 100% reduction from pre-census to post-census bait take after treatment against *R. rattus*.

A palatability study has also been submitted which demonstrates a 65.6% mean palatability

of the paste bait against *R. rattus* with 100% mortality in 8 days.

Conclusions: We believe that this data is acceptable and sufficient to support the claim against Black rats (*R. rattus*). This data has been generated to support the general claim "against rats".

Efficacy Data against *M. musculus*:

Meta-SPC 1: Grain Bait:

Two palatability studies using grain bait against *M.musculus* have been submitted. These studies show 60.2% and 85.3% palatability, 100% mortality was observed at 8 and 11 days respectively.

A wet aged bait palatability study has also been submitted to support the use in sewers against mice. However, as mice are not a significant problem in sewers, this data was not considered.

One semi-field pen trial has been submitted to support use of grain bait against mice, which shows 23.20% palatability and 100% mortality in 14 days.

Two field trials have been submitted which show 89.80% and 93% reduction in bait take after treatment.

As this formulation does not contain a preservative, a palatability study using aged grain bait against *M. musculus* has been submitted. This study shows a 34.2% palatability and 100% mortality was observed in 6 days.

Conclusions: The data provided was sufficient to support the claim against House mice (*M. musculus*) at the first authorisation. We believe this data is still valid and acceptable as no changes have been made to the product formulation.
Data on aged bait has been provided to extend the product shelf life to 2 years.

Meta-SPC 2: Paste Bait

A palatability study that demonstrates 44.10% palatability of the paste bait against *M.musculus* with 100% mortality in 5 days has been submitted.

A semi-field pen trial has also been submitted that shows 46.55% palatability and 100% mortality in 6 days against mice.

Two field trials have been submitted to support use of paste bait against mice. The first of these studies show 88.2% reduction in bait take after treatment and a 93.9% tracking score reduction. The second study shows 92.4% bait take reduction and 94.8% tracking score reduction

Due to a formulation change, a new palatability study was provided to demonstrate that the changes on the formulation do not affect the product efficacy. The new palatability study shows a 40.8% palatability of the paste bait against *M.musculus* with 100% mortality in 4 days. Based on this data, we can conclude that all the existing efficacy data applies to the new formulation.

Conclusions: The data provided was sufficient to support the claim against House mice (*M. musculus*) at the first authorisation. Due to the formulation change, a new palatability study was carried out which demonstrates that the new formulation is sufficiently similar to the

previous one. Therefore, all the efficacy data generated for the paste product is still valid and acceptable.

3.5.5 Conclusion on efficacy

The product family claims the following:

• General public use

A grain bait containing brodifacoum (0.0025% w/w) for use as a rodenticide for the control of rats and mice indoors, outdoors (around buildings).

• Professional use (including professional and trained professional users)

Trained professional users: A grain bait containing brodifacoum (0.0025% w/w) for use as a rodenticide for the control of rats and mice indoors, outdoors (around buildings) and in sewers.

Professional users: A grain bait containing brodifacoum (0.0025% w/w) for use as a rodenticide for the control of rats and mice indoors, outdoors (around buildings).

Trained professional or professional users: A paste bait containing brodifacoum (0.0025% w/w) for use as a rodenticide for the control of rats and mice indoors and outdoors (around buildings).

According to the Technical Notes for Guidance (TNsG) products for use against rats and mice should have mortality/potency, palatability and field trial data demonstrating efficacy against *R. norvegicus*, *R. rattus* and *M. musculus*.

The paste bait contains a preservative and therefore it was not necessary to carry out further *in vivo* testing to demonstrate the effectiveness of 24 month aged palatability.
For the grain bait, a palatability study for each target organism (*R. norvegicus*, *R. rattus* and *M. musculus*) has been provided and therefore this product can be authorised with a shelf life claim of 24 months.

3.5.6 Occurrence of resistance and resistance management

Refer to Document IIIA Section 5.7.1 and 5.7.2 for details about the potential for the development of resistance to Brodifacoum, and management strategies.
Please refer to the Letter of Access for Brodifacoum, allowing use of this data to support this application for product authorisation of Brodifacoum Family – PT14. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use.
To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients

3.5.7 Known limitations

There are no known limitations for the Brodifacoum family – PT14.
The products must be used in tamper-resistant bait stations or in suitably covered and protected bait points.

3.5.8 Relevant information if the BPF is intended to be authorised for use with other biocidal products

Not applicable.

3.6 Risk assessment for human health

No change.

3.6.1 Assessment of effects on human health

3.6.1.1 Skin corrosion and irritation

3.6.1.2 Eye irritation

3.6.1.3 Respiratory tract irritation

3.6.1.4 Skin sensitization

3.6.1.5 Respiratory sensitization

3.6.1.6 Acute oral toxicity

3.6.1.7 Acute inhalation toxicity

3.6.1.8 Acute dermal toxicity

3.6.2 Information on dermal absorption

3.6.3 Available toxicological data relating to substance(s) of concern

3.6.4 Other

3.6.4.1 Food and feeding stuffs studies

3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal products

3.6.4.3 Other test(s) related to the exposure to humans

3.6.5 Available toxicological data relating to endocrine disruption

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

3.6.6.2 Identification of the main paths of human exposure towards active substance(s) and substance(s) of concern from use in the BPF

3.6.6.3 List of exposure scenarios

3.6.6.4 Overview of BPF: worst case uses and corresponding exposure scenarios

3.6.6.5 Reference values to be used in risk characterisation

3.6.6.6 Specific reference value for groundwater

3.6.6.7 Professional users (including industrial users and trained professional users)

3.6.6.8 Non-professional users

3.6.6.9 Secondary exposure to professional bystanders and non-professional bystanders/general public

3.6.7 Monitoring data

3.6.8 Dietary risk assessment

3.6.8.1 Information of non-biocidal use of the active substance and residue definitions

3.6.8.2 Estimating livestock exposure to active substances used in biocidal products and Worst Case Consumer Exposure (WCCE)

3.6.8.3 Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s) and consumer exposure

3.6.8.4 Estimating transfer of biocidal active substances into foods as a result of non-professional use and consumer exposure

3.6.8.5 Maximum residue limits or equivalent

3.6.9 Aggregated exposure and risk characterisation

3.6.10 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

3.6.11 Overall conclusion on risk assessment for human health

3.7 Risk assessment for animal health

No change.

3.7.1 Risk for companion animals

3.7.2 Risk for livestock animals

3.8 Risk assessment for the environment

No change.

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance(s), metabolite(s), and transformation product(s)

3.8.1.2 Endpoints for the products

3.8.1.3 Substance(s) of concern

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

3.8.2 Emission estimation

3.8.2.1 General information

3.8.2.2 Emission estimation for the scenario(s)

3.8.3 Exposure calculation and risk characterisation

3.8.4 Primary and secondary poisoning

3.8.4.1 Primary poisoning

3.8.4.2 Secondary poisoning

3.8.5 Mixture toxicity

3.8.6 Aggregated exposure (combined for relevant emission sources)

3.8.7 Overall conclusion on the risk assessment for the environment

3.9 Assessment of a combination of biocidal products

No change.

3.10 Comparative assessment

No change.

3.10.1 Screening phase

3.10.2 Tier IA

3.10.3 Tier IB

3.10.4 Tier II

3.10.5 Overall conclusion

4 Appendices

4.1 Calculations for exposure assessment

No change.

4.1.1 Human health

4.1.2 Dietary assessment

4.1.3 Environment

4.2 New information on the active substance(s) and substance(s) of concern

No change.

4.3 List of studies for the biocidal product family

Table 4.1 List of studies for the biocidal product family

Author (s)	**Year** **Report date**	**Reference No.** ***(Annex III requirement)*** **/** **IUCLID Section No.**	**IUCLID Document name**	**Title.** **Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/No)**	**Data Protection Claimed (Yes/No)**
Boffa Miskell Limited	2017	6.7/ Section 6.7.6	B5.10/12	Rentokil Brodifacoum Paste Bait Efficacy Field Trial on Norway Rats Report (Waller Road)	ORG	N/A	NO	Yes
Boffa Miskell Limited	2017	6.7/ Section 6.7.7	B5.10/13	Rentokil Brodifacoum Paste Bait Efficacy Field Trial on Norway Rats Report (Schlaepfer Road) Rats Report (Waller Road)	ORG	N/A	NO	Yes
Boffa Miskell Limited	2017	6.7/ Section 6.7.9	B5.10/14	Rentokil Brodifacoum Paste Bait Efficacy Field Trial on mice Report (Maketu Road)	ORG	N/A	NO	Yes

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
Boffa Miskell Limited	2017	6.7/ Section 6.7.10	B5.10/15	Rentokil Brodifacoum Paste Bait Efficacy Field Trial on Mice Report (Dazeley Road)	ORG	N/A	NO	Yes
Chambers SG & Snowdon PJ	2004	Section 13	Doc IIC/01	Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits	ORG	CEFIC EBPF Rodenticide Data Development Group	NO	Yes
IZInovation	2020	6.7/ Section 6.7.16	B5.10/28	Evaluation of the Efficacy of the bait "Brodifacoum Grain Bait" for the control of black rat infestations in and around buildings, One field trial Rhone, France, 2020.	ORG	N/A	NO	Yes

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
IZInovation	2020	6.7/ Section 6.7.17	B5.10/29	Evaluation of the Efficacy of the bait "Brodifacoum Grain Bait" for the control of black rat infestations in and around buildings, One field trial Rhone, France, 2020.	ORG	N/A	NO	Yes
IZInovation	2020	6.7/ Section 6.7.18	B5.10/30	Evaluation of the Efficacy of the bait "Brodifacoum 25 Paste" for the control of black rat infestations in and around buildings, One field trial Rhone, France, 2020	ORG	N/A	NO	Yes
IZInovation	2020	6.7/ Section 6.7.19	B5.10/31	Rodenticide palatability and efficacy study of the Brodifacoum 25 pmm Paste in Black rat (*Rattus rattus*), 2020	ORG	N/A	NO	Yes

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
IZInovation	2019	6.7/ Section 6.7.22	B5.10/34	Evaluation of the Efficacy of Paste bait for the control of the Black rat infestation in and around agricultural buildings. One field trial: Isere, France, 2019.	ORG	N/A	NO	Yes
IZInovation	2021	6.7/ Section 6.7.23	B5.10/35	Rodenticide Palatability and Efficacy Study of the 0.0025% w/w Brodifacoum Grain Bait in Black rat (*Rattus rattus*)	ORG	N/A	NO	Yes
Rentokil Initial plc	2016	6.7/ Section 6.7.1	B5.10/01	Bioassay of 25ppm Brodifacoum Grain vs Rats & Mice - Initial Storage Stability Trial	ORG	N/A	NO	Yes
Rentokil Initial plc	2016	6.7/ Section 6.7.1; 6.7.3 and 6.7.20	B5.10/03	Bioassay of 25ppm Brodifacoum Paste and grain vs.mice@21°C	ORG	N/A	NO	Yes

Author (s)	**Year** **Report date**	**Reference No.** ***(Annex III requirement)*** **/** **IUCLID Section No.**	**IUCLID Document name**	**Title.** **Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/No)**	**Data Protection Claimed (Yes/No)**
Rentokil Initial plc	2016	6.7/ Section 6.7.1; 6.7.3 and 6.7.20	B5.10/04	Bioassay of 25ppm Brodifacoum Paste and grain vs.rats@21°C	ORG	N/A	NO	Yes
Rentokil Initial plc	2017	6.7/ Section 6.7.2	B5.10/08	Semi-field trial of 25ppm Brodifacoum Grain vs wild Oaklease mice	ORG	N/A	NO	Yes
Rentokil Initial plc	2017	6.7/ Section 6.7.5	B5.10/09	Damp conditions palatability trial vs Rats and Mice	ORG	N/A	NO	Yes
Rentokil Initial plc	2017	6.7/ Section 6.7.4	B5.10/10	Semi-field trial of 25ppm Brodifacoum Paste vs Wild Oaklease mice – Trial 1	ORG	N/A	NO	Yes

Author (s)	**Year** **Report date**	**Reference No.** ***(Annex III requirement)*** **/** **IUCLID Section No.**	**IUCLID Document name**	**Title.** **Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/No)**	**Data Protection Claimed (Yes/No)**
Rentokil Initial 1927 plc	2017	6.7/ Section 6.7.8	B5.10/20	Rodenticide Efficacy Field Trial: Brodifacoum paste formulation (0.0025% brodifacoum) against Brown Rat (*Rattus norvegicus*) at Chiquitos - Medway Valley Leisure Park (Chariot Way, Rochester, ME2 2FF)	ORG	N/A	NO	Yes

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
Rentokil Initial 1927 plc	2017	6.7/ Section 6.7.11	B5.10/23	Rodenticide Efficacy Field Trial: Brodifacoum Grain (0.0025% Brodifacoum) against House mice (Mus domesticus) at Homebase Orpington, Sevenoaks Way Industrial Estate, Main Road, St Paul's Cray Orpington, BR5 3UH	ORG	N/A	NO	Yes
Rentokil Initial 1927 plc	2017	6.7/ Section 6.7.13	B5.10/24	Rodenticide Efficacy Field Trial: Brodifacoum Grain (0.0025% brodifacoum) against Brown Rat (*Rattus norvegicus*) at Twycross Zoo (Burton Rd, Atherstone, CV9 3PX) Field Trial Site A. 'The Farm'.	ORG	N/A	NO	Yes

Author (s)	**Year** **Report date**	**Reference No.** ***(Annex III requirement)*** **/** **IUCLID Section No.**	**IUCLID Document name**	**Title.** **Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/No)**	**Data Protection Claimed (Yes/No)**
Rentokil Initial 1927 plc	2017	6.7/ Section 6.7.12	B5.10/25	Rodenticide Efficacy Field Trial: Brodifacoum Loose Grain (0.0025% brodifacoum) against House Mice (Mus domesticus) at Twycross Zoo (Burton Rd, Atherstone, CV9 3PX) Field Trial Site B. Gibbon Forest	ORG	N/A	NO	Yes
Rentokil Initial 1927 plc	2017	6.7/ Section 6.7.14	B5.10/26	Rodenticide Efficacy Field Trial: Brodifacoum loose grain (0.0025% brodifacoum) against Brown rats (*Rattus norvegicus*) at M20 Motorway Services, Stop 24 Services, Stanford Intersection, J11, Hythe, CT21 4BL	ORG	N/A	NO	Yes

Author (s)	**Year** **Report date**	**Reference No.** ***(Annex III requirement)*** **/ IUCLID Section No.**	**IUCLID Document name**	**Title. Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/No)**	**Data Protection Claimed (Yes/No)**
Rentokil Initial 1927 plc	2017	6.7/ Section 6.7.15	B5.10/27	Rodenticide Efficacy Field Trial: Brodifacoum loose grain (0.0025% brodifacoum) against Brown Rat (*Rattus norvegicus*) at Twycross Zoo (Burton Rd, Atherstone, CV9 3PX) Field Trial Site B. 'The Compound'.	ORG	N/A	NO	Yes
Rentokil Initial	2019	6.7/ Section 6.7.20	B5.10/32	Bioassay of 25ppm Brodifacoum Paste (Initial Shelf life) vs TO mice & Wistar rats	ORG	N/A	NO	Yes
Rentokil Initial	2018	6.7/ Section 6.7.21	B5.10/33	Bioassay of 25ppm Brodifacoum Grain (24 month shelf life) vs TO mice & Wistar rats	ORG	N/A	NO	Yes

Author (s)	**Year** **Report date**	**Reference No.** ***(Annex III requirement)*** **/** **IUCLID Section No.**	**IUCLID Document name**	**Title.** **Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/No)**	**Data Protection Claimed (Yes/No)**
Rentokil Initial	2018	Section 3.4.1 – Brodifacoum Grain	B3.7/09	Storage Stability: Brodifacoum Grain Bait	ORG	N/A	Yes	Yes
Rentokil Initial	2021	Section 3.4.1 – Brodifacoum Paste	B3.7/11	24 Month Storage Stability: Brodifacoum 25 Paste with BIT	ORG	N/A	NO	Yes
Rentokil Initial plc	2016	Section 5 – Brodifacoum grain	B4.1/01	Method Validation: Brodifacoum Grain Bait	ORG	N/A	yes	Yes
Rentokil Initial plc	2021	Section 5 – Brodifacoum Paste	B4.1/02	Method Validation: Brodifacoum 25 Paste	ORG	N/A	yes	Yes

4.4 References

4.4.1 References other than list of studies for the BPF

A) Safety data sheets

Author (s)	Year Report date	IUCLID Document name	Title.
Pelgar	2019	B2.2/01	Safety Data Sheet for Brodifacoum (EU)
Syngenta	2019	B2.2/01.1	Safety Data Sheet for Brodifacoum TC
Samuel Banner and Co. Ltd	2014	B2.2/02	Safety Data Sheet for Monopropylene Glycol
Lacrosse Milling Company	2017	B2.2/03	Safety Data Sheet for Wheat Products
Fiorio Colori Spa	2016	B2.2/04	Safety Data Sheet for E133 BRILLIANT BLUE FCF
Fiorio Colori Spa	2013	B2.2/04.1	Specifications for E133 BRILLIANT BLUE FCF
BASF SE	2020	B2.2/05	Safety Data Sheet for Heliogen Blue D 7086
Macfarlan Smith Ltd	2015	B2.2/06	Safety Data Sheet for Bitrex 2.5%(w/v) in Water
Macfarlan Smith Ltd	2016	B2.2/07	Safety Data Sheet for Bitrex 25% (w/v) in Propylene Glycol
IMCD UK Ltd.	2018	B2.2/08	Safety Data Sheet for Antracine 12 BHA
IMCD UK Ltd.	2018	B2.2/09	Safety Data Sheet for Antrancine BHT
AAK (UK) Limited	2016	B2.2/10	Safety Data Sheet for Akoflake P05/MB
Pura Foods Ltd	2016	B2.2/11	Safety Data Sheet for Ambrex
Whitworth Bros. Ltd.	2015	B2.2/12	Product specification for Wheat flour
ADM, Pura Foods Limited	2017	B2.2/15	Product specification for Golden Veltex Shortening
Thor Specialities (UK) Ltd	2016	B2.2/17	Safety Data Sheet for Acticide B 20 (N)
Tennants Distribution Ltd	2021	B2.2/18	Safety Data Sheet for Citric Acid Monohydrate

4.4.2 Guidance documents

- HEEG opinion12 - HEEG opinion on an Harmonised approach for the assessment of rodenticides (anticoagulant)
- HEEG opinion 10 - HEEG opinion on Harmonising the number of manipulations in the

assessment of rodenticides (anticoagulants) (Doc IIC-06)
- Dermal absorption values for anticoagulant rodenticides: Alternative approach for the occupational setting, agreed at Human Health Working Group meeting WG-I-2021 , Publication date: 1 June 2021, issued by BAuA
- Dermal absorption values for anticoagulant rodenticides issued by the Federal Institute for Risk Assessment (BfR), agreed at Human Health Working Group meeting WG-I-2021 and published on 1st June 2021
- Assessment Report for Brodifacoum, Product-type 14(Rodenticide) issued by Italy, revised 16 December 2010
- Product Assessment Report for Brodifacoum Paste (50ppm), issued by Ireland, 2014
- Product Assessment Report for Brodifacoum family, issued by the UK, November 2017
- Revised Emission Scenario Document for Product Type 14, Rodenticides, 2018, issued by ECHA
- Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 3.0 April 2018

4.4.3 Legal texts

- Regulation (EU) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
- Regulation (EU) No 528/2012 of the European Parliament and of the Council of of 22 May 2012 concerning the making available on the market and use of biocidal products

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.