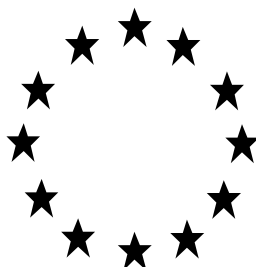


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL
PRODUCT FOR THE RENEWAL OF A NATIONAL
AUTHORISATION**



Product identifier in R4BP	BONIRAT CEBO FRESCO
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Difenacoum
Case No. in R4BP	BC-XL037089-16
Asset No. in R4BP	ES-0012124-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/BB(MR)-2018-14-00275
Date	February 2018

Table of content

1	Conclusion	3
2	Summary of the product assessment	5
2.1	Administrative information	5
2.2	Composition and formulation.....	6
2.3	Classification and Labelling according to the Regulation (EC) No 1272/2008.....	7
2.4	Use(s) appropriate for further authorisation	7
2.5	General directions for use	22
3	Assessment of the product	28
3.1	Use(s) considered appropriate for authorisation after former assessment (uses evaluated by Spain)	28
3.2	Physical, chemical and technical properties.....	30
3.3	Physical hazards and respective characteristics.....	32
3.4	Methods for detection and identification.....	32
3.5	Efficacy against target organisms	32
3.6	Risk assessment for human health	32
3.7	Risk assessment for animal health.....	56
3.8	Risk assessment for the environment	56
3.9	Assessment of a combination of biocidal products	58
3.10	Comparative assessment	59
4	Confidential annex (Access level: “Restricted” to applicant and authority).....	60
4.1	Full composition of the product	60
4.2	List of studies for the biocidal product (Confidential data)	61

1 Conclusion

BONIRAT PASTE BAIT was authorised in UK in August 2011 and under the name IBYSRAT CEBO FRESCO by mutual recognition with Spain in 2013.

BONIRAT CEBO FRESCO was authorised in Spain in May 2015 according to Implementing Regulation (UE) n° 414/2013. In October 2017 was authorised a major change requested by the applicant. The major change consisted in the decrease of the active substance concentration difenacoum from 50ppm to 29ppm.

It is concluded after evaluation of data submitted that the ready-to-use product, BONIRAT CEBO FRESCO, with the active substance bromadiolone, at a level of 0.0029% w/w, may be authorised for use as a rodenticide (product-type 14). Some of conclusions to the previous assessment remains valid and the new information provided by the applicant for the renewal allow granting the authorisation.

The conclusions about physical hazards and methods for detection and identification remain valid to the previous evaluation and no new information has been submitted.

The conclusion about the efficacy against target organisms remains valid.

According to Commission Regulation (EU) 2016/1179 the product BONIRAT CEBO FRESCO, with the active substance difenacoum, at a level of 0.0029% w/w is classified as SPECIFIC TARGET ORGAN TOXICITY AFTER REPEATED EXPOSURE. CATEGORY 2 (STOT RE 2); H373 May cause damage to organs (blood) through prolonged or repeated exposure.

Regarding the exposure assessment, according to the HEEG Opinion 9 (Default protection factors for protective clothing and gloves), the protection factor due to the use of gloves is modified from 90% to 95% (for challenges by a solid).

Regarding the risk assessment for the environment the conclusion from the former assessment remains valid. However, the new threshold value in groundwater for difenacoum of 0.01 µg/L used for the risk assessment ECHA/BPC/112/2016, has to be considered for the re-assessment of the product.

The overall conclusion is that the intended uses of BONIRAT CEBO FRESCO do not pose an unacceptable risk to the sewage treatment plant, soil, air, surface water, sediment, and groundwater compartments. An unacceptable risk is however identified for the primary and secondary poisoning of

non-target vertebrates and specific risk mitigation measures on the use of the product are required to reduce the risk for the environment.

The risk for primary poisoning can be significantly reduced by deploying baits so that they cannot be reached by the non-target animals, using the baits in tamper-resistant bait stations, and applying the paste formulations only inside buildings. The risk for secondary poisoning is more difficult to control, as poisoned rodents may be available for predators for several days after intake of difenacoum. One way to reduce the risk is to limit the field of use of paste baits to indoor use only. Carcasses and unconsumed baits must be collected during and after the control campaign to reduce the secondary poisoning.

Therefore, BONIRAT CEBO FRESCO, can be authorised as a rodenticide product against house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*). It is to be used indoors, outdoors around buildings and outdoor in open areas and waste dumps. The users can be general public, professional and trained professional.

The specific intended uses of the product are in section 2.4. of this assessment report.

Spanish CA grants the use of BONIRAT CEBO FRESCO according to the table 5 included in this assessment report and according to our national risk mitigation measures.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

BONIRAT CEBO FRESCO
Additional names: DIFETEC P-29 BONIRAT NEXT PASTA BONIRAT NEXT PASTA PLUS BONIRAT SENSITIVE PASTA BONIRAT SENSITIVE PASTA PLUS ZED DF SENSITIVE PASTA ZED DF SENSITIVE PASTA PLUS STEGORAT NEXT PASTA STEGORAT NEXT PASTA PLUS STEGORAT SENSITIVE PASTA STEGORAT SENSITIVE PASTA PLUS BONITOP SENSITIVE PASTA BONITOP SENSITIVE PASTA PLUS RATIDIF SENSITIVE PASTA RATICIDA IBYS 200-D CUCHOL RATICIDA CEBO FRESCO-D ZYNRAT DN PASTA FRESCA PASTA FRESCA DF CQM

2.1.2 Manufacturer(s) of the product

Name of manufacturer	Zapi S.p.A.
Address of manufacturer	Via Terza Strada 12 35026 Conselve (PD) Italy
Location of manufacturing sites	Via Terza Strada 12 35026 Conselve (PD) Italy

2.1.3 Manufacturer(s) of the active substance(s)

Active substance	DIFENACOUM
Name of manufacturer	ACTIVA S.r.l. / Dr. TEZZA S.r.l.
Address of manufacturer	ACTIVA S.r.l. Via Feltre, 32 20132 – Milano - ITALY
Location of manufacturing sites	Dr. TEZZA S.r.l. Via Tre Ponti, 22 37050 – S. Maria di Zevio (VR) ITALY

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	Active substance	56073-07-5	259-978-4	0.0029
-	-	Non-active substances	-	-	-

- The product contains a bittering agent and dye.
 - Information on the full composition is provided in the confidential annex (see chapter 4).
- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012

2.2.2 Information on the substance(s) of concern

No substance of concern was identified upon initial assessment (the application for authorisation was submitted and the assessment took place before the Biocidal Products Regulation 528/2012 entered into force).

2.2.3 Type of formulation


Ready-to-use bait: Paste

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008

Table 2

Classification	
Hazard classes, Hazard categories	Hazard statements
Specific target organ toxicity after repeated exposure. Category 2	H373

Table 3

Labelling		
	Code	Pictogram / Wording
Pictograms	GHS08	
Signal word		WARNING
Hazard statements	H373	May cause damage to organs (blood) through prolonged or repeated exposure
Supplemental hazard information	-	
Supplemental label elements	-	
Precautionary statements	P102	Keep out of reach of children
	P103	Read label before use.
	P280	Wear protective gloves.
	P501	Dispose of contents and/ or container as a hazardous waste to a registered establishment or undertaking, in accordance with current regulations
Note	-	

2.4 Use(s) appropriate for further authorisation

In order to make proper use of the standard sentences for SPCs for rodenticides it is considered necessary to split the uses currently evaluated in Spain further down:

Table 4

Use(s) considered appropriate for authorisation after former assessment (uses currently evaluated in SPAIN)		Use(s) appropriate for further authorisation	
1	House mice and/or brown rats – general public– in and around buildings	1	House mice– general public - indoor
		2	Brown Rats – general public - indoor
		3	Brown Rats – general public – outdoor around buildings
2	House mice and/or brown rats – professionals – in and around buildings	4	House mice – professionals - indoor
		5	Brown Rats – professionals - indoor
		6	House mice and/or Brown rats – Professionals – outdoor around buildings
3	House mice and/or brown rats – trained professionals – in and around buildings, open areas and waste dumps.	7	House mice and/or Brown rats – trained professionals - indoor
		8	House mice and/or Brown rats – trained professionals – outdoor around buildings
		9	Brown Rats – trained professionals – outdoor open areas & waste dumps

Uses authorised in Spain according national Risk Mitigation Measures

Table 5

Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain)	Use(s) appropriate for authorisation in Spain according national Risk Mitigation Measures.
House mice and/or brown rats – general public– in and around buildings	House mice– general public - indoor
	Brown rats – general public - indoor
	Brown Rats – general public – outdoor around buildings
House mice and/or brown rats – professional– in and around buildings	House mice – professionals - indoor
	Brown Rats – professionals - indoor
	Brown Rats – Professionals – outdoor around buildings
House mice and/or brown rats – trained professionals – in and around buildings, open areas and waste dumps.	House mice and/or Brown rats – trained professionals - indoor
	House mice and/or Brown rats – trained professionals – outdoor around buildings
	Brown Rats – trained professionals – outdoor open areas & waste dumps

2.4.1 Use 1– House mice – general public – indoor

Product Type(s)	14
-----------------	----

Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice)
Field(s) of use	Indoor.
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: 50g of product per bait point each 2-5m 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2-5 meters (2m in case of strong infestation and 5m in case of weak infestation).
Category(ies) of users	General public
Pack sizes and packaging material	Maximum pack size of 50g. Number of packed bags per packaging: up to 50g Grams/kg of bait per packed bag: individual sachets of 10/ 15 g Packaging material: Pot, box, bucket, tub and bag Material: plastic, printed fibre, and cardboard box.

2.4.1.1. Use-specific instructions for use

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

2.4.1.2 Use-specific risk mitigation measures

See section 2.5.2.

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

- See section 2.5.3.

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

See section 2.5.4.

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

See section 2.5.5.

2.4.2 Use 2 - Rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Rattus norvegicus</i> (brown rats)
Field(s) of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: 100g of product per bait point each 5-10m 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum pack size of 150g. Number of packed bags per packaging: up to 150g Grams/kg of bait per packed bag: individual sachets of 10/ 15 g Packaging material: Pot, box, bucket, tub and bag Material: plastic, printed fibre, and cardboard box.

2.4.2.1 Use-specific instructions for use

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

2.4.2.2 Use-specific risk mitigation measures

See section 3.5.2.

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

See section 3.5.3.

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

See section 3.5.3.

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

See section 3.5.5

2.4.3 Use 3– Brown Rats – general public – Outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Rattus norvegicus</i> (brown rats)
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: 100g of product per bait point each 5-10m 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).
Category(ies) of users	General public
Pack sizes and packaging material	Maximum pack size of 150g. Number of packed bags per packaging: up to 150g Grams/kg of bait per packed bag: individual sachets of 10/ 15 g Packaging material: Pot, box, bucket, tub and bag Material: plastic, printed fibre, and cardboard box.

2.4.3.1 Use-specific instructions for use

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

2.4.3.2 Use-specific risk mitigation measures

- See section 2.5.2

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

- See section 2.5.3.

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

See section 2.5.4

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

See section 2.5.5

2.4.4. Use 4- House mice – professionals – indoor

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

Field(s) of use	Indoor.
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: 50g of product per bait point each 2-5m 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2-5 meters (2m in case of strong infestation and 5m in case of weak infestation).
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: individual sachets of 10/ 15 g. Tubes up to 600 g. and bags up to 1Kg. Packaging material: Pot, box, bucket, tub and bag Material: plastic, printed fibre, and cardboard box.

2.4.4.1 Use-specific instructions for use

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

2.4.4.2 Use-specific risk mitigation measures

See section 2.5.2

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

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

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

See section 2.5.4

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

See section 2.5.5

2.4.5 Use 5 – Brown Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Rattus norvegicus</i> (brown rats)
Field(s) of use	Indoor.
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rat: 100g of product each 5-10m 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: individual sachets of 10/ 15 g. Tubes up 600 g. and bags of 1Kg. Packaging material: Pot, box, bucket, tub and bag Material: plastic, printed fibre, and cardboard box.

2.4.4.1 Use-specific instructions for use

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

2.4.4.2 Use-specific risk mitigation measures

See section 2.5.2

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

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

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

See section 2.5.4

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

See section 2.5.5

2.4.6 Use 6 – House mice and/or brown rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rats)
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: 100 g of product each 5-10m 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation). Mice: 50 g of product each 2-5m. 50 g of bait per bait station. If more than one bait station is needed,

	the minimum distance between bait stations should be of 2-5meters (2m in case of strong infestation and 5m in case of weak infestation).
Category(ies) of users	Professionals
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: individual sachets of 10/ 15 g. Tubes up to 600 g .and bags up to 1Kg. Packaging material: Pot, box, bucket, tub and bag Material: plastic, printed fibre, and cardboard box.</p>

2.4.6.1 Use-specific instructions for use

<ul style="list-style-type: none"> - Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding. - The bait stations should be visited [<i>for mice</i> - at least every 2 to 3 days at] [<i>for rats</i> - only 5 to 7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. - Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. - Follow any additional instructions provided by the relevant code of best practice.

2.4.6.2 Use-specific risk mitigation measures

<ul style="list-style-type: none"> - Do not apply this product directly in the burrows

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

<ul style="list-style-type: none"> - When placing bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

See section 2.5.4

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

See section 2.5.5

2.4.7 Use 7 - House mice and/or brown rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rats)
Field(s) of use	Indoor
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: 100g per baiting point Mice: 50g per baiting point
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: individual sachets of 10/ 15 g. Tubes up 600 g Packaging material: Pot, box, bucket, tub and bag Material: plastic, printed fibre, and cardboard box.

2.4.7.1 Use-specific instructions for use

- Remove the remaining product at the end of treatment period.
- Follow any additional instructions provided by the relevant code of best practice.

2.4.7.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as

possible) to improve product intake and reduce the likelihood of reinvasion.

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use the product in pulsed baiting treatments.
- This product shall only be used indoors and in places that are not accessible to children or non-target animals.

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

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

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

See section 2.5.4.

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

See section 2.5.5.

2.4.8 Use 8– House mice and/or brown rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rats)
Field(s) of use	Outdoor around buildings
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and	Rats: 100g per baiting point

frequency	Mice: 50g per baiting point
Category(ies) of users	Trained professionals
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: individual sachets of 10/ 15 g. Tubes up 600 g Packaging material: Pot, box, bucket, tub and bag Material: plastic, printed fibre, and cardboard box</p>

2.4.8.1 Use-specific instructions for use

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

2.4.8.2 Use-specific risk mitigation measures

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

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

- When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes,

irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

See section 2.5.4

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

See section 2.5.5

2.4.9 Use 9 – Brown Rats – trained professionals – Outdoor open areas & waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Rattus norvegicus</i> (brown rats)
Field(s) of use	Outdoor open areas Outdoor waste dumps
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: 100g per baiting point
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: individual sachets of 10/ 15 g. Tubes up 600 g Packaging material: Pot, box, bucket, tub and bag Material: plastic, printed fibre, and cardboard box

2.4.9.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the bait stations in areas not liable to flooding.

- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period
- Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species
- Follow any additional instructions provided by the relevant code of best practice

2.4.9.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

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

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

See section 2.5.4

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

See section 2.5.5

2.5 General directions for use

2.5.1 Instructions for use

General Public:

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- [Do not open the sachets containing the bait - *where relevant for the bait formulation in the product*].
- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Do not place bait stations near water drainage systems where they can come into contact with water.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- Remove the remaining bait or the bait stations at the end of the treatment period.

Professionals:

- Read and follow the product information as well as any information accompanying the product or

provided at the point of sale before using it.

- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Bait stations should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (*see section 5.3 for the information to be shown on the label*).
- When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely those there are resistant rodents so consider the use of a non-anticoagulant

rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

- Remove the remaining bait or the bait stations at the end of the treatment period.
- Do not open the sachets containing the bait.

Trained professionals:

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (*see section 5.3 for the information to be shown on the label*).
- When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Do not open the sachets containing the bait

2.5.2 Risk mitigation measures:

General Public:

- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
- The product information (i.e. label and/or leaflet) shall clearly show that:
 - The product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
 - Users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").
 - Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
 - Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
 - Dispose dead rodents in accordance with local requirements [*The method of disposal shall be*

described specifically in the national SPC and be reflected on the product label].

Professionals:

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- The product information (i.e. label and/or leaflet) shall clearly show that:
the product shall not be supplied to the general public (e.g. "for professionals only").
the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service
- Do not wash the bait stations with water between applications.
- Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*

Trained Professionals:

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").

- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.

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

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

2.5.4 Instructions for safe disposal of the product and its packaging

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

reflected on the product label].

- Use of gloves are recommended.

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

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

2.5.6 Other information

- Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after consumption of the bait.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- This product contains a bittering agent and a dye.
- For general public: The package of the product should be fitted with a tactile warning

3 Assessment of the product

3.1. Use(s) considered appropriate for authorisation after former assessment (uses evaluated by Spain)

3.1.1 Use 1– House mice and/or brown rats– general public – in and around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Rattus norvegicus</i> (brown rats) <i>Mus musculus</i> (house mice)
Field(s) of use	In and around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and	For mice: High level of infestation: 50 g bait per bait point (every 2 m).

frequency	Low level of infestation: 50 g bait per bait point (every 5 m). For rats: High level of infestation: 100 g bait per bait point (every 5 m). Low level of infestation: 100 g bait per bait point (every 10 m).
Category(ies) of users	General public
Pack sizes and packaging material	10 g sachets in container: 50, 100, 200, 250, 300, 350, 400, 450, 500, 550, 600, 650, 700, 750, 800, 850, 900, 950 and 1000g. 15 g sachets in container: 60, 105, 210, 255, 300, 360, 405, 450, 510, 555, 600, 660, 705, 750, 810, 855, 900 and 960 g. Pre-dosed tamper resistant bait stations each containing 10, 15, 20, 30, 40, 45, 50, 90 and 100 g of 10 g and 15 g sachets. Containers: buckets, cardboard box, cardboard carton, plastic tank, plastic bag

3.1.2 Use 2 – House mice and/or brown rats– professional– in and around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Rattus norvegicus</i> (brown rats) <i>Mus musculus</i> (house mice)
Field(s) of use	In and around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice: High level of infestation: 50 g bait per bait point (every 2 m). Low level of infestation: 50 g bait per bait point (every 5 m). For rats: High level of infestation: 100 g bait per bait point (every 5 m). Low level of infestation: 100 g bait per bait point (every 10 m)
Category(ies) of users	Professional
Pack sizes and packaging material	10 g sachets in container: 50, 100, 200, 250, 300, 350, 400, 450, 500, 550, 600, 650, 700, 750, 800, 850, 900, 950 and 1000g. 15 g sachets in container: 60, 105, 210, 255, 300, 360, 405, 450, 510, 555, 600, 660, 705, 750, 810, 855, 900 and 960 g. Pre-dosed tamper resistant bait stations each containing 10, 15, 20, 30, 40, 45, 50, 90 and 100 g of 10 g and 15 g sachets. Containers: buckets, cardboard box, cardboard carton, plastic tank, plastic bag

3.1.3 Use 3– House mice and/or brown rats– trained professional– in and around buildings, open areas and waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Rattus norvegicus</i> (brown rats) <i>Mus musculus</i> (house mice)
Field(s) of use	In and around buildings, open areas and waste dumps
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice: High level of infestation: 50 g bait per bait point (every 2 m). Low level of infestation: 50 g bait per bait point (every 5 m). For rats: High level of infestation: 100 g bait per bait point (every 5 m). Low level of infestation: 100 g bait per bait point (every 10 m)
Category(ies) of users	trained professional
Pack sizes and packaging material	10 / 15 g sachets in container: 30, 40, 45, 50 100, 200, 250, 300, 400, 500, 600, 700, 800, 900 and 1000 g. 2, 3, 4, 5, 10, 15, and 25kg. Plastic tray with printed peel-off covering: 50 and 100 g. Plastic tube (for use with caulking gun): 50, 100, 200, 250, 300, 400, 500 and 600g. Containers: buckets, cardboard box, cardboard carton, plastic tank, plastic bag, plastic tube, plastic tray.

3.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference						
Storage stability test – accelerated storage	CIPAC MT46.3	0.0029	Difenacoum active ingredient initial content: 0.0028 ± 0.0005% w/w Difenacoum active ingredient final content: 0.0027 ± 0.0001% w/w $\Delta[C] = -3.57\%$ The result complies with the tolerance value (-10%).	IUCLID 3.4.1						
			<table border="1"> <thead> <tr> <th>Test</th> <th>Initial</th> <th>Final</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Test	Initial	Final				
Test	Initial	Final								

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results			Reference
				value	value	
			Relative density (20°C)	1.1882 g/mL	1.1926 g/mL	
			<p>Conclusion: No change in the sample appearance, colour, odour, weight variation and relative density was found for the test item stored in plastic bags after 12 weeks of storage at 35°C, and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging. Therefore, it can be concluded that the sample of Difenacoum 0.0029% w/w pasta bait formulation is stable in its commercial packaging under the accelerated storage conditions.</p>			
Storage stability test – long term storage at ambient temperature	Guidance on Data Requirements for Active Substances and Biocidal Products	0.0029	<p>Difenacoum active ingredient initial content: 0.0028 ± 0.0001% w/w</p> <p>Difenacoum active ingredient final content: 0.0026 ± 0.0001% w/w</p> <p>Δ[C] = -7.14% The result complies with the tolerance value (-10%).</p>			
				Initial value	Final value	
			Relative density (20°C)	1.1882 g/mL	1.545 g/mL	IUCLID 3.4.1
			<p>Conclusion: No change in the sample appearance, colour, and odour was found in the formulation stored in a polyethylene bag containing single dose paper sachets for 24 months of storage at ambient warehouse temperature and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena. Therefore, it can be concluded that the sample of</p>			

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Difenacoum 0.0029% w/w pasta bait formulation is stable in its commercial packaging under the accelerated storage conditions.	

Apart from the properties mentioned above, neither new data was not provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding those physical, chemical and technical properties not provided remains valid.

3.3 Physical hazards and respective characteristics

Neither new data was not 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.

3.4 Methods for detection and identification

Neither new data was not provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

3.5 Efficacy against target organisms

Neither new data was not provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding efficacy against target organisms remains valid.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Neither new data was not provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding effects of the active substance on human health remains valid.

3.6.2 Assessment of effects of the product on human health

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding effects of the product on human health remains valid.

3.6.3 Exposure assessment

Regarding human exposure no studies have been submitted; therefore, the exposure assessment has been performed using the paper "HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants)" agreed at TMII 2011. This paper was based on an operator exposure study conducted by CEFIC/EBPF Rodenticides Data Development Group (Chambers et al. (2004)» and the number of manipulations agreed at TMII 2010.

According to the HEEG Opinion 9 (Default protection factors for protective clothing and gloves), the protection factor due to the use of gloves is modified from 90% to 95% (for challenges by a solid).

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure						
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure		
	Trained professional use	Professional use	General public (Non-professional)	Trained Professional use	Professional use	General public
Inhalation	No	No	No	No	No	No
Dermal	Yes	Yes	Yes	Yes	Yes	Yes
Oral	n.a.	n.a.	n.a.	No	No	Yes

List of scenarios

Summary table: scenarios			
Scenario number	Scenario	Primary or secondary exposure Description of scenario	Exposed group

Summary table: scenarios			
1.	Application (loading and placing bait boxes)	Primary exposure. During use, user will be exposed through the loading of bait. Exposure will be via the dermal route and to the hands only. 1.1. saquets 1.2. trays 1.3. caulking gun	Trained professional user, professional users, general public (non-professional)
2.	Post-application (Cleaning)	Primary exposure. During disposal, users will be exposed through the disposal of used bait and carcasses. Exposure will be via dermal route and to the hands only. 2.1 .sachets 2.2. trays 2.3. caulking gun	Trained professional user, professional users, general public (non-professional)
3.	Ingestion of bait by children	Secondary exposure: "transient mouthing of poison bait" scenario. Either 5g (User Guidance) or 10mg (TNsG) of the product is assumed to be swallowed by an infant per poisoning event.	Bystanders (children, infants and adults)

Professional exposure

Trained professionals (pest Control Operators)

3.6.3.1: sachets

Scenario [1] – Loading and placing sachets

Description of Scenario [1] - Trained professional user (Pest Control Operator)		
<p>During the process of loading the bait (worse case: sachets of 10 g in bait boxes of 100 g), the user may be exposed by dermal contact to the bait. Trained professional users are bounded to use PPE during the development of the different tasks of their work.</p> <p>Total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).</p>		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	Amount of exposure to product during loading (for one bait point):	27.79 mg b.p. / 5 contacts x 10 contacts = 55.58 mg b.p
	Number of manipulations during loading:	60
Tier 2	PPE (gloves)	5%

Calculations for Scenario [1]

Summary table: estimated exposure from trained professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 / No PPE	-	7.41×10^{-7} mg/kg bw/day	-	7.41×10^{-7} mg/kgbw/day
Scenario [1]	Tier 2 / PPE(gloves)	-	3.7×10^{-8} mg/kg bw/day	-	3.7×10^{-8} mg/kg bw/day

Scenario [2] – Cleaning

Description of Scenario [2] - Trained professional uses (Pest Control Operator)		
During the process of cleaning the bait, the user may be exposed by dermal contact to the bait. Trained professional users are bounded to use PPE during the development of the different tasks of his work. The total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	Amount of exposure to product during claning:	5.7 mg b.p
	Number of manipulations during cleaning:	15
Tier 2	PPE (gloves)	5%

Calculations for Scenario [2]

Summary table: estimated exposure from trained professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2]	Tier 1 / No PPE	-	1.90×10^{-8} mg/kg bw/day	-	1.90×10^{-8} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	9.5×10^{-10} mg/kg bw/day	-	9.5×10^{-10} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from trained professional users				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios [1 + 2] – Tier 1	-	7.6×10^{-7} mg/kg bw/day	-	7.6×10^{-7} mg/kg bw/day
Scenarios [1 + 2] – Tier 2	-	3.8×10^{-8} mg/kg bw/day	-	3.8×10^{-8} mg/kg bw/day

3.6.3.2: trays

Scenario [1] – Loading and placing trays

Description of Scenario [1] - Trained professional user (Pest Control Operator)		
<p>During the process of loading the bait (worse case: trays of 50 g in bait points of 100 g), the user may be exposed by dermal contact to the bait. Trained professional users are bounded to use PPE during the development of the different tasks of their work.</p> <p>Total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).</p>		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	Amount of exposure to product during loading (for one bait point):	27.79 mg b.p. / 5 contacts x 2 contacts = 11.116 mg b.p
	Number of manipulations during loading:	60
Tier 2	PPE (gloves)	5%

Calculations for Scenario [1]

Summary table: estimated exposure from trained professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 / No PPE	-	1.48×10^{-7} mg/kg bw/day	-	1.48×10^{-7} mg/kg bw/day
Scenario [1]	Tier 2 / PPE(gloves)	-	7.41×10^{-9} mg/kg bw/day	-	7.41×10^{-9} mg/kg bw/day

Scenario [2] – Cleaning

Description of Scenario [2] - Trained professional uses (Pest Control Operator)
During the process of cleaning the bait, the user may be exposed by dermal contact to the bait. Trained

Description of Scenario [2] - Trained professional uses (Pest Control Operator)		
professional users are bounded to use PPE during the development of the different tasks of his work. The total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	Amount of exposure to product during claning:	5.7 mg b.p
	Number of manipulations during cleaning:	15
Tier 2	PPE (gloves)	5%

Calculations for Scenario [2]

Summary table: estimated exposure from trained professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2]	Tier 1 / No PPE	-	1.90×10^{-8} mg/kg bw/day	-	1.90×10^{-8} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	9.5×10^{-10} mg/kg bw/day	-	9.5×10^{-10} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from trained professional users				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios [1 + 2] – Tier 1	-	1.67×10^{-7} mg/kg bw/day	-	1.67×10^{-7} mg/kg bw/day
Scenarios [1 + 2] – Tier 2	-	8.36×10^{-9} mg/kg bw/day	-	8.36×10^{-9} mg/kg bw/day

3.6.3.3: Caulking guns

There is no agreement on how caulking guns should be treated in the HEEG opinion 12.

There is also no specific exposure scenario in the TNsG to cover application from caulking guns or anything similar.

Therefore, a reverse scenario approach is used, based on application of wood preservatives by trowel (reference; example in human exposure to biocidal products, TNsG 2007).

Scenario [1] – Loading and placing caulking guns

Description of Scenario [1] - Trained professional user (Pest Control Operator)		
During the process of loading the bait, the user may be exposed by dermal contact to the bait. Trained professional users are bounded to use PPE during the development of the different tasks of their work. Total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	AEL (chronic)	$1.1 \cdot 10^{-6}$ mg/kg pc/day
Tier 2	PPE (gloves)	5%

Calculations for Scenario [1]

Summary table: estimated exposure from trained professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 / No PPE	-	4.947×10^3 mg	-	4.947×10^3 mg
Scenario [1]	Tier 2 / PPE(gloves)	-	98.95×10^3 mg	-	98.95×10^3 mg

Professional user3.6.3.1: sachetsScenario [1] – Loading and placing sachets

Description of Scenario [1] – professional users		
During the process of loading the bait (worse case: sachets of 10g in bait boxes of 100g), the user may be exposed by dermal contact to the bait. Professional users are bounded to use PPE during the development of the different tasks of their work. Total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	Amount of exposure to product during loading (for one bait point):	27.79 mg b.p. / 5 contacts x 10 contacts = 55.58 mg b.p

Description of Scenario [1] – professional users		
	Number of manipulations during loading:	5
Tier 2	PPE (gloves)	5%

Calculations for Scenario [1]

Summary table: estimated exposure from professional					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 / No PPE	-	6.17×10^{-8} mg/kg bw/day	-	6.17×10^{-8} mg/kg bw/day
Scenario [1]	Tier 2 / PPE(gloves)	-	3.08×10^{-9} mg/kg bw/day	-	3.08×10^{-9} mg/kg bw/day

Scenario [2] – Cleaning

Description of Scenario [2] - professional users		
During the process of cleaning the bait, the user may be exposed by dermal contact to the bait. Professional users are bounded to use PPE during the development of the different tasks of their work. The total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	Amount of exposure to product during claning:	5.7 mg b.p
	Number of manipulations during cleaning:	5
Tier 2	PPE (gloves)	5%

Calculations for Scenario [2]

Summary table: estimated exposure from professional users					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2]	Tier 1 / No PPE	-	6.33×10^{-9} mg/kg bw/day	-	6.33×10^{-9} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	3.16×10^{-10} mg/kg bw/day	-	3.16×10^{-10} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from professional users				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios [1 + 2] – Tier 1	-	6.8×10^{-8} mg/kg bw/day	-	6.8×10^{-8} mg/kg bw/day
Scenarios [1 + 2] – Tier 2	-	3.41×10^{-9} mg/kg bw/day	-	3.41×10^{-9} mg/kg bw/day

3.6.3.2: traysScenario [1] – Loading and placing trays

Description of Scenario [1] – professional users		
<p>During the process of loading the bait (worse case: trays of 50g in bait points of 100g), the user may be exposed by dermal contact to the bait. Professional users are bounded to use PPE during the development of the different tasks of their work.</p> <p>Total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).</p>		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	Amount of exposure to product during loading (for one bait point):	27.79 mg b.p. / 5 contacts x 2 contacts = 11.116 mg b.p
	Number of manipulations during loading:	5
Tier 2	PPE (gloves)	5%

Calculations for Scenario [1]

Summary table: estimated exposure from professional					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 / No PPE	-	1.23×10^{-8} mg/kg bw/day	-	1.23×10^{-8} mg/kg bw/day
Scenario [1]	Tier 2 / PPE(gloves)	-	6.17×10^{-10} mg/kg bw/day	-	6.17×10^{-10} mg/kg bw/day

Scenario [2] – Cleaning

Description of Scenario [2] - professional users		
During the process of cleaning the bait, the user may be exposed by dermal contact to the bait. Professional users are bounded to use PPE during the development of the different tasks of his work. The total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	Amount of exposure to product during claning:	5.7 mg b.p
	Number of manipulations during cleaning:	5
Tier 2	PPE (gloves)	5%

Calculations for Scenario [2]

Summary table: estimated exposure from professional users					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2]	Tier 1 / No PPE	-	6.33×10^{-9} mg/kg bw/day	-	6.33×10^{-9} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	3.16×10^{-10} mg/kg bw/day	-	3.16×10^{-10} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from professional users				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios [1 + 2] – Tier 1	-	1.87×10^{-8} mg/kg bw/day	-	1.87×10^{-8} mg/kg bw/day
Scenarios [1 + 2] – Tier 2	-	9.35×10^{-10} mg/kg bw/day	-	9.35×10^{-10} mg/kg bw/day

3.6.3.3: Caulking guns

There is no agreement on how caulking guns should be treated in the HEEG opinion 12.

There is also no specific exposure scenario in the TNsG to cover application from caulking guns or anything similar.

Therefore, a reverse scenario approach is used, based on application of wood preservatives by trowel (reference; example in human exposure to biocidal products, TNsG 2007).

Scenario [1] – Loading and placing caulking guns

Description of Scenario [1] - professional user (Pest Control Operator)		
During the process of loading the bait, the user may be exposed by dermal contact to the bait. Professional users are bounded to use PPE during the development of the different tasks of their work. Total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	AEL (chronic)	$1.1 \cdot 10^{-6}$ mg/kg pc/day
Tier 2	PPE (gloves)	5%

Calculations for Scenario [1]

Summary table: estimated exposure from trained professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 / No PPE	-	4.947×10^3 mg	-	4.947×10^3 mg
Scenario [1]	Tier 2 / PPE(gloves)	-	98.95×10^3 mg	-	98.95×10^3 mg

General public (non-professional)3.6.3.1: sachetsScenario [1] – Loading and placing sachets

Description of Scenario [1] – General public (non-professional)		
During the process of loading the bait (worse case: sachets of 10g in bait boxes of 100g), the user may be exposed by dermal contact to the bait. Non-professional users are not bounded to use PPE during the development of the different tasks of their work. Total systemic exposure has been assessed without (Tier 1).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg

Description of Scenario [1] – General public (non-professional)		
	Amount of exposure to product during loading (for one bait station):	27.79 mg b.p. / 5 contacts x 10 contacts = 55.58 mg b.p
	Number of manipulations during loading:	5

Calculations for Scenario [1]

Summary table: estimated exposure from General public (non-professional)					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 / No PPE	-	6.17×10^{-8} mg/kgbw/day	-	6.17×10^{-8} mg/kgbw/day

Scenario [2] – Cleaning

Description of Scenario [2] - General public (non-professional)		
<p>During the process of cleaning the bait, the user may be exposed by dermal contact to the bait. Non-professional users are not bounded to use PPE during the development of the different tasks of his work.</p> <p>The total systemic exposure has been assessed without (Tier 1).</p>		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	Amount of exposure to product during claning:	5.7 mg b.p
	Number of manipulations during cleaning:	5

Calculations for Scenario [2]

Summary table: estimated exposure from General public (non-professional)					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2]	Tier 1 / No PPE	-	6.33×10^{-9} mg/kg bw/day	-	6.33×10^{-9} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from General public (non-professional)				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios [1 + 2] – Tier 1	-	6.81×10^{-8} mg/kg bw/day	-	6.81×10^{-8} mg/kg bw/day

3.6.3.2: trays

Scenario [1] – Loading and placing trays

Description of Scenario [1] – General public (non-professional)		
<p>During the process of loading the bait (worse case: trays of 50 g in bait points of 100 g), the user may be exposed by dermal contact to the bait. Non-professional users are not bounded to use PPE during the development of the different tasks of their work.</p> <p>Total systemic exposure has been assessed without (Tier 1).</p>		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	Amount of exposure to product during loading:	27.79 mg b.p. / 5 contacts x 2 contacts = 11.116 mg b.p
	Number of manipulations during loading:	5

Calculations for Scenario [1]

Summary table: estimated exposure from- General public (non-professional)					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 / No PPE	-	1.23×10^{-8} mg/kgbw/day	-	1.23×10^{-8} mg/kgbw/day

Scenario [2] – Cleaning

Description of Scenario [2] - General public (non-professional)
<p>During the process of cleaning the bait, the user may be exposed by dermal contact to the bait. Non-professional users are not bounded to use PPE during the development of the different tasks of his work.</p> <p>The total systemic exposure has been assessed without (Tier 1).</p>

Description of Scenario [2] - General public (non-professional)		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	Amount of exposure to product during claning:	5.7 mg b.p
	Number of manipulations during cleaning:	5

Calculations for Scenario [2]

Summary table: estimated exposure from General public (non-professional)					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2]	Tier 1 / No PPE	-	6.33×10^{-9} mg/kg bw/day	-	6.33×10^{-9} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from General public (non-professional)				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios [1 + 2] – Tier 1	-	1.87×10^{-8} mg/kg bw/day	-	1.87×10^{-8} mg/kg bw/day

3.6.3.3: Caulking guns

There is no agreement on how caulking guns should be treated in the HEEG opinion 12.

There is also no specific exposure scenario in the TNsG to cover application from caulking guns or anything similar.

Therefore, a reverse scenario approach is used, based on application of wood preservatives by trowel (reference; example in human exposure to biocidal products, TNsG 2007).

Scenario [1] – Loading and placing caulking guns

Description of Scenario [1] - General public (non-professional)
During the process of loading the bait, the user may be exposed by dermal contact to the bait. Non-professional users are not bounded to use PPE during the development of the different tasks of their work. Total systemic exposure has been assessed without (Tier 1)

Description of Scenario [1] - General public (non-professional)		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.046%
	Operator body weight:	60 kg
	AEL (acute)	1.1 10 ⁻⁶ mg/kg bw/day

Calculations for Scenario [1]

Summary table: estimated exposure from General public (non-professional)					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 / No PPE	-	4.947 x 10 ³ mg/day	-	4.947 x 10 ³ mg/day

Exposure of the general public

Scenario [3]

In order to minimise the risk of ingestion of the bait by humans, the bait contains a bittering aversive agent. The bait stations have been manufactured to prevent incidental poisoning to both non-target animals and human, i.e. children. Bait stations are done in hard plastic and are locked to prevent access to the bait. If bait stations are not used, the bait point should be covered or protected in such a way to prevent access to the bait. However, indirect exposure, especially of children, may happen.

Description of Scenario [3]			
<p>Where appropriate, exposure assessments are based on default values in EU Guidance documents. However, the default value when handling dead rodents is considered unrealistic and therefore, the potential exposure due to dermal contact with poisoned rodents is not included in the risk assessment because the available scenarios are unrealistic.</p> <p>For oral exposure of toddlers two sub-scenarios are made:</p> <p>(3.a) with 10 mg bait (default value for bait treated with repellent) and</p> <p>(3.b) with 5 grams for bait without aversive agent (TNSG on Human Exposure to Biocidal Products, User Guidance).</p> <p>Trained professional users should dispose unused or part-consumed products. Bait stations protect the product and should prevent access by infants (worse-case).</p>			
	<table border="1"> <thead> <tr> <th>Parameters</th> <th>Value</th> </tr> </thead> </table>	Parameters	Value
Parameters	Value		

Description of Scenario [3]		
Tier 1	Infants Body weight	10 kg
	A.S. content of BP	0.0029%
	3.a. Quantity ingested (g)	0.01
	3.b. Quantity ingested (g)	5

Calculations for Scenario [3]

Summary table: systemic exposure from general public					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [3.b]	Tier 1 / No PPE	-	-	0.0145 mg/kg bw/d	0.0145 mg/kg bw/d
Scenario [3.a]		-	-	2.9×10^{-5} mg/kg bw/d	2.9×10^{-5} mg/kg bw/d

Further information and considerations on scenario [3]

These values assume ingestion of bait, however, the presence of denatonium benzoate as an aversive agent and the location of the bait in a sealed bait station and in an inaccessible area have always been considered enough to mitigate the risk. Since the bittering agent is not 100% efficient in protecting against ingestion in all children, it is therefore important that the bait stations are kept out of reach of children (and other non-target species, including pets and livestock) during storage and use.

Monitoring data

The exposure assessment has been performed using the following papers:

- "HEEG Opinion 12 on an harmonised approach for the assessment of rodenticides (anticoagulants)" agreed at TMII 2011. This paper was based on an operator exposure study conducted by CEFIC/EBPF Rodenticides Data Development Group (Chambers *et al.* (2004)) and the number of manipulations has been proposed by the applicant.
- "HEEG Opinion 10 on harmonizing the number of manipulations in the assessment of rodenticides (anticoagulants)".
- Default human factor values have been set following the Recommendation n° 14 (BPC Ad hoc WG).
- "HEEG Opinion 9. Default protection factors for protective clothing and gloves".

Note: It has not been considered, but we could have been taken into account the conclusions reached in the WGV2017_TOX_7-2a (Harmonisation PT 14 exposure assessment 10 November 2017) regarding reduction of the exposure that offers the additional protection of the sachet based on its

material (eg paper, plastic, etc). For plastic sachets the protection factor cannot currently be set, but in any case it will be at least 50%.

Dietary exposure

Not applicable: non exposure is foreseen because the bait boxes with the product must not be placed where food, feeding stuffs, drinking water and surfaces where food is prepared can become contaminated.

Exposure associated with production, formulation and disposal of the biocidal product

Please see scenario [2] of exposure assessment which is related with disposal of the biocidal product.

Aggregated exposure

No aggregated exposure is foreseeable since the product is not intended to be used under another biocidal product type.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	Exposed group	Tier/PPE	Estimated total uptake
1 Sachets	Trained-professional	Tier 2 / PPE	3.7×10^{-8} mg/kg bw/day
1 Sachets	Trained-professional	Tier 1/ no PPE (unrealistic)	7.41×10^{-7} mg/kg bw/day
2 Sachets	Trained-professional	Tier 2/ PPE	9.5×10^{-10} mg/kg bw/day
2 Sachets	Trained-professional	Tier 1/ no PPE (unrealistic)	1.90×10^{-8} mg/kg bw/day
1 Trays	Trained-professional	Tier 2 / PPE	7.41×10^{-9} mg/kg bw/day
1 Trays	Trained-professional	Tier 1/ no PPE (unrealistic)	1.48×10^{-7} mg/kg bw/day
2 Trays	Trained-professional	Tier 2/ PPE	9.5×10^{-10} mg/kg bw/day
2 Trays	Trained-professional	Tier 1/ no PPE (unrealistic)	1.90×10^{-8} mg/kg bw/day
1 C. Gun	Trained-professional	Tier 2 / PPE	98.95×10^3 mg/day
1 C. Gun	Trained-professional	Tier 1/ no PPE (unrealistic)	4.947×10^3 mg/day
1 Sachets	Professional	Tier 2 / PPE	3.08×10^{-9} mg/kg bw/day
1 Sachets	Professional	Tier 1/ no PPE (unrealistic)	6.17×10^{-8} mg/kg bw/day
2 Sachets	Professional	Tier 2/ PPE	3.16×10^{-10} mg/kg bw/day
2 Sachets	Professional	Tier 1/ no PPE (unrealistic)	6.33×10^{-9} mg/kg bw/day
1 Trays	Professional	Tier 2 / PPE	6.17×10^{-10} mg/kg bw/day
1 Trays	Professional	Tier 1/ no PPE (unrealistic)	1.23×10^{-8} mg/kg bw/day

Scenarios and values to be used in risk assessment			
2 Trays	Professional	Tier 2/ PPE	3.16×10^{-10} mg/kg bw/day
2 Trays	Professional	Tier 1/ no PPE (unrealistic)	6.33×10^{-9} mg/kg bw/day
1 C. Gun	Professional	Tier 2 / PPE	98.95×10^3 mg/day
1 C. Gun	Professional	Tier 1/ no PPE (unrealistic)	4.947×10^3 mg/day
1 Sachets	General public (non-professional)	Tier 1/ no PPE (unrealistic)	6.17×10^{-8} mg/kg bw/day
2 Sachets	General public (non-professional)	Tier 1/ no PPE (unrealistic)	6.33×10^{-9} mg/kg bw/day
1 Trays	General public (non-professional)	Tier 1/ no PPE (unrealistic)	1.23×10^{-8} mg/kg bw/day
2 Trays	General public (non-professional)	Tier 1/ no PPE (unrealistic)	6.33×10^{-9} mg/kg bw/day
1 C. Gun	General public (non-professional)	Tier 1/ no PPE (unrealistic)	4.947×10^3 mg
3.b	Bystander (toddler)	Without aversive / No PPE	0.0145 mg/kg bw/d
3.a	Bystander (toddler)	With aversive / No PPE	2.9×10^{-5} mg/kg bw/d

3.6.4 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL) (mg/kg bw/day)	AF ¹	Correction for oral absorption	Value (mg/kgbw/day)
AEL _{acute}	-	0.00034	300 (+ factor 2 to extrapolation from LOAEL)	-	1.1×10^{-6}
AEL _{medium-term}	-	0.00034		-	1.1×10^{-6}
AEL _{long-term}	-	0.00034		-	1.1×10^{-6}
ARfD	Not applicable	-	Not applicable	-	Not applicable
ADI	Not applicable	-	Not applicable	-	Not applicable

¹Assessment factor have been obtained from the Difenacoum's CAR.

3.6.4.1 Risk for professional users

Risk for trained professional users

Systemic effects

Sachets

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Loading / Scenario [1]	Tier 1	0.00034	1.1×10^{-6}	7.41×10^{-7}	67.4	Yes
	Tier 2			3.7×10^{-8}	3.3	Yes
Cleaning / Scenario [2]	Tier 1			1.90×10^{-8}	1.7	Yes
	Tier 2			9.5×10^{-10}	0.08	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1] + [2]	Tier 1	0.00034	1.1×10^{-6}	7.6×10^{-7}	69.1	Yes
	Tier 2			3.8×10^{-8}	3.4	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

Exposure for trained professional operators applying 'difenacoum 0.0029% w/w paste bait' for control of rats and mice is acceptable without the use of PPE and no risk is foreseeable and therefore its use is considered acceptable. In any case, for trained professional users wearing gloves it is a necessary practice regardless of the risk characterization.

Trays

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Loading / Scenario [1]	Tier 1	0.00034	1.1×10^{-6}	1.48×10^{-7}	13.48	Yes
	Tier 2			7.41×10^{-9}	0.67	Yes
Cleaning / Scenario [2]	Tier 1			1.90×10^{-8}	1.73	Yes
	Tier 2			9.5×10^{-10}	0.08	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1] + [2]	Tier 1	0.00034	1.1×10^{-6}	1.67×10^{-7}	15.2	Yes
	Tier 2			8.36×10^{-9}	0.76	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

Exposure for trained professional operators applying 'difenacoum 0.0029% w/w paste bait' for control of rats and mice is acceptable without use of PPE and no risk is foreseeable and therefore its use is considered acceptable. In any case, wearing gloves it is a necessary practice for trained professional users, regardless of the risk characterization.

Caulking guns

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/day
Loading / Scenario [1]	Tier 1	0.00034	1.1×10^{-6}	4947
	Tier 2			98950

Local effects

There is no need to consider local effects separately.

Conclusion

This calculation predicts that the acceptable daily dose would be equivalent to 4.9 g of the biocidal product contaminating the unprotected hands of a trained professional user or 98.9 g of the product on protective gloves worn by the user. It is unlikely that a trained professional operator following good practise (such as releasing the caulking gun pressure after each application to prevent continued extrusion) would achieve that level of contamination.

Therefore its use is considered acceptable. In any case, wearing gloves it is a necessary practice for trained professional users, regardless of the risk characterization.

3.6.4.2 Risk for professional users and General public (non-professional)

Sachets

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Loading / Scenario [1]	Tier 1	0.00034	1.1×10^{-6}	6.17×10^{-8}	5.62	Yes
	Tier 2			3.08×10^{-9}	0.28	Yes
Cleaning / Scenario [2]	Tier 1			6.33×10^{-9}	0.58	Yes
	Tier 2			3.16×10^{-10}	0.028	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1] + [2]	Tier 1	0.00034	1.1×10^{-6}	6.81×10^{-8}	6.19	Yes
	Tier 2			3.41×10^{-9}	0.31	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

Exposure for professional operators applying 'difenacoum 0.0029% w/w paste bait' for control of rats and mice is acceptable without the use of PPE. On the other hand, when the product is applied under label recommendations and using PPE (gloves) no risk is foreseeable and therefore its use is considered acceptable

Trays

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Loading / Scenario [1]	Tier 1	0.00034	1.1×10^{-6}	1.23×10^{-8}	1.12	Yes
	Tier 2			6.17×10^{-10}	0.05	Yes
Cleaning / Scenario [2]	Tier 1			6.33×10^{-9}	0.58	Yes
	Tier 2			3.16×10^{-10}	0.028	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1] + [2]	Tier 1	0.00034	1.1×10^{-6}	1.86×10^{-8}	1.69	Yes
	Tier 2			9.35×10^{-10}	0.08	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

Exposure for professional operators applying 'difenacoum 0.0029% w/w paste bait' for control of rats and mice is acceptable without the use of PPE. On the other hand, when the product is applied under

label recommendations and using PPE (gloves) no risk is foreseeable and therefore its use is considered acceptable

Caulking guns

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/day
Loading / Scenario [1]	Tier 1	0.00034	1.1×10^{-6}	4947
	Tier 2			98950

Local effects

There is no need to consider local effects separately.

Conclusion

It is unlikely that an operator following good practise (such as releasing the caulking gun pressure after each application to prevent continued extrusion) would achieve that level of contamination. Therefore its use is considered acceptable.

3.6.4.3 Risk for the general public (Secondary exposure)

Adults or children may be present following application and may be incidentally exposed by touching unprotected bait under an hypothetical worse case as the product is placed inside a bait station. For products applied in bait stations or outdoors, incidental exposure will be very limited.

Child are potentially the group most at risk as they may play inside or around buildings where baits have been placed. They could be exposed orally by chewing bait or touching their mouth with contaminated fingers.

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL _{acute} mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Bait without aversive agent [3.b]	Tier 1- (no PPE)	0.00034	1.1×10^{-6}	0.0145	1.3181×10^6	No
Bait with aversive agent [3.a]				2.9×10^{-5}	2636	No

Local effects

There is no need to consider local effects separately.

Conclusion

In the hypothetical case that a child may enter in contact with unprotected bait, the calculated exposure was 2636 % of AEL based on a default exposure value which assumes that infants might ingest 10 mg of poison bait and 1.31×10^6 % of AEL when assuming that children might ingest 5 g bait. These values show that infants and children ingesting bait might be at risk. In this hypothetical worst case scenario, firstly, the bait is located inside a sealed bait station and secondly, the product contains a bittering agent which would prevent ingestion of the baits. Therefore, in practice the margins of safety are expected to be much higher than those calculated. It is also important that product labels and good practice advise users to prevent access to bait by children.

The proposed uses therefore represent an acceptable risk from indirect exposure.

3.6.4.4 Risk for consumers via residues in food

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

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

There is no risk derived from a combined exposure because indirect exposure via the environment is considered negligible, the product is not intended to be mixed with other biocidal or non biocidal products and the product does not contain any other active substance of concern.

Summary of risk characterisation

Scenario number	Exposed group	Tier/PPE	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
1 Sachets	Trained professional user	Tier 1	1.1×10^{-6}	7.41×10^{-7}	67.4	Yes
1 Sachets	Trained professional user	Tier 2	1.1×10^{-6}	3.7×10^{-8}	3.3	Yes
2 Sachets	Trained professional user	Tier 1	1.1×10^{-6}	1.90×10^{-8}	1.7	Yes
2 Sachets	Trained professional user	Tier 2	1.1×10^{-6}	9.5×10^{-10}	0.08	Yes

Scenario number	Exposed group	Tier/PPE	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
1 + 2 Sachets	Trained professional user	Tier 1	1.1×10^{-6}	7.6×10^{-7}	69.1	Yes
1 + 2 Sachets	Trained professional user	Tier 2	1.1×10^{-6}	3.8×10^{-8}	3.4	Yes
1 Trays	Trained professional user	Tier 1	1.1×10^{-6}	1.48×10^{-7}	13.8	Yes
1 Trays	Trained professional user	Tier 2	1.1×10^{-6}	7.41×10^{-9}	0.67	Yes
2 Trays	Trained professional user	Tier 1	1.1×10^{-6}	1.9×10^{-8}	1.7	Yes
2 Trays	Trained professional user	Tier 2	1.1×10^{-6}	9.5×10^{-10}	0.08	Yes
1 + 2 Trays	Trained professional user	Tier 1	1.1×10^{-6}	1.67×10^{-7}	15.2	Yes
1 + 2 Trays	Trained professional user	Tier 2	1.1×10^{-6}	8.36×10^{-9}	0.7	Yes
1 Sachets	Professional user and General Public	Tier 1	1.1×10^{-6}	6.17×10^{-8}	5.6	Yes
1 Sachets	Professional user	Tier 2	1.1×10^{-6}	3.08×10^{-9}	0.28	Yes
2 Sachets	Professional user and General Public	Tier 1	1.1×10^{-6}	6.33×10^{-9}	0.57	Yes
2 Sachets	Professional user	Tier 2	1.1×10^{-6}	3.16×10^{-10}	0.028	Yes
1 + 2 Sachets	Professional user and General Public	Tier 1	1.1×10^{-6}	6.81×10^{-8}	6.19	Yes
1 + 2 Sachets	Professional user	Tier 2	1.1×10^{-6}	3.41×10^{-9}	0.3	Yes
1 Trays	Professional user and General Public	Tier 1	1.1×10^{-6}	1.23×10^{-8}	1.12	Yes
1 Trays	Professional user	Tier 2	1.1×10^{-6}	6.17×10^{-10}	0.05	Yes

Scenario number	Exposed group	Tier/PPE	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
2 Trays	Professional user and General Public	Tier 1	1.1×10^{-6}	6.33×10^{-9}	0.57	Yes
2 Trays	Professional user	Tier 2	1.1×10^{-6}	3.16×10^{-10}	0.028	Yes
1 + 2 Trays	Professional user and General Public	Tier 1	1.1×10^{-6}	1.87×10^{-8}	1.69	Yes
1 + 2 Trays	Professional user	Tier 2	1.1×10^{-6}	9.35×10^{-10}	0.08	Yes
3.b without aversive	Bystander (children)	Tier 1	1.1×10^{-6}	0.0145	1.318×10^6	No
3.a with aversive	Bystander (children)	Tier 2	1.1×10^{-6}	2.9×10^{-5}	2636	No

3.7 Risk assessment for animal health

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding animal health remains valid.

3.8 Risk assessment for the environment

Neither new data was not provided nor had new guidance to be taken into account for re-assessment performed with the new substance active concentration. Accordingly, the conclusion from the former assessment regarding the environment remains valid.

3.8.1 Exposure assessment

Neither new data was not provided nor had new guidance to be taken into account for re-assessment performed with the new substance active concentration. Accordingly, the conclusion from the former assessment regarding the environment remains valid.

3.8.2 Risk characterisation

Neither new data was not provided nor had new guidance to be taken into account for re-assessment performed with the new substance active concentration. Accordingly, the conclusion from the former assessment regarding the environment remains valid.

However, the new threshold value in groundwater for difenacoum of 0.01 µg/L used for the risk assessment ECHA/BPC/112/2016, has to be considered for the re-assessment of the product.

Groundwater

Concentrations in soil pore water were calculated for the use of 'BONIRAT CEBO FRESCO' in all proposed scenarios: in and around buildings, open areas and waste dumps. According to ESD and TGN the potential exposure to STP and surface water (and hence sediment) from the proposed use is considered to be negligible.

Exposure to groundwater was derived from PEC_{soil} for open areas scenario and the new threshold value in groundwater for difenacoum of 0.01 µg/L was used for the risk assessment ECHA/BPC/112/2016. PEC_{localsoil} value for open areas scenario has been calculated using the worst case default values taken from the ESD (for PT 14 biocides used as rodenticides, EUBEES 2003), assuming that impregnated grain is applied directly into rat holes. This is in effect the highest concentrations of a.s that could be found in soil from the agreed ESD use of a rodenticide product assuming a product concentration of a.s. at 29 ppm (0.0029 %). Hence any groundwater concentration calculated from this worst case will be protective for any situation whereby a lower dosage/ fraction of active in the product/ or application frequency in the product exists.

Note this worst case soil value may not correspond to that specifically relating to this product- but can be considered to be worst case and hence protective for the groundwater].

Therefore, PEC_{gw} was calculated from the derived PEC_{soil} for open areas scenario, using the following equation (ECHA guidance on environmental risk assessment, Volume IV, part B):

$$PEC_{localsoil_{porewater}} = PEC_{localsoil} \times RHO_{soil} / (K_{soil-water} \times 1000)$$

$$PEC_{gw} = 1.09 \times 10^{-2} \text{ µg/L}$$

Conclusion: Considering a PEC_{gw} value 1.09×10^{-2} µg/L, the risk is unacceptable for the "open area" scenario. Hence, as a tier 2, a FOCUS modelling was realized to refine the PEC groundwater for the "open areas" scenario.

Parameters use in FOCUS:

Model used	FOCUS PEARL
Years of simulation	1
Application rate	0.001005 kg/ha (open areas)
Standard crop for arable land	Maize (for agricultural soil) Grass (alfalfa)
Application depth	Incorporation 0 cm
Date of application	12 application per year
Molar mass	444.5 g.mol ⁻¹
Vapour pressure	< 10 ⁻⁶ Pa at 20°C
Water solubility	1.7 mg.L ⁻¹ at 20°C
K _{ow}	1048266.3 L.kg ⁻¹ at 20°C
Freundlich exponent	1
DT50soil	833 d at 12°C
Coefficient for uptake for plant	0

The same results were obtained for all scenarios, see the following table:

LOCATION	MAIZE	ALFALFA
CHATEAUDUN	0.00000	0.00000
HAMBURG	0.00000	0.00000
JOKIOINEN	0.00000	0.00000
KREMSMUENSTE	0.00000	0.00000
OKEHAMPTON	0.00000	0.00000
PIACENZA	0.00000	0.00000
PORTO	0.00000	0.00000
SEVILLA	0.00000	0.00000
THIVA	0.00000	0.00000

According to the FOCUS modelling, the risk is acceptable in groundwater for the use of BONIRAT CEBO FRESCO in all scenarios.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

As difenacoum is a Candidate for Substitution, a comparative assessment must be carried out as part of the evaluation process.

The Biocidal Products Committee of the European Chemicals Agency published its Opinion on Questions regarding the comparative assessment of anticoagulant rodenticides on 02 March 2017 (Document no. ECHA/BPC/145/2017).

The Decision states that:

- In the absence of anticoagulant rodenticides, the use of rodenticide biocidal products containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also show some significant practical or economical disadvantages for the relevant uses.
- There is insufficient scientific evidence to prove that non-chemical alternative methods of rodent control are sufficiently effective according to the criteria established in agreed Union guidance with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

The Decision forms the basis of the COMMISSION IMPLEMENTING DECISION (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

On the basis of this comparative assessment, the authorisation of rodenticide products containing difenacoum is justified.