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	RATOTER RATONICIDA
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Difenacoum
Case No. in R4BP	BC-ES000471-43
Asset No. in R4BP	ES-0001378-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/APP(NA)-2018-14-00089
Date	February 2018

Table of content

1 Conclusion

The assessment presented in this report has shown that the ready-to-use product, RATOTER RATONICIDA, with the active substance difenacoum, at a level of 0.005% w/w, may be authorised for use as a rodenticide (product-type 14) since the conclusions of initial evaluation remain valid.

However, the biocidal product RATOTER RATONICIDA contains 0.005 %w/w difenacoum and the Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures has been applied.

Due to national legislation in relation to categories of users which three categories of users are established (general public, professional and trained professional user) based on the qualification obtained, therefore the professional is extrapolated to the general public (under this national regulation the professional user is not bounded to use PPE when they apply the product). For that, the biocidal product rodenticides containing 0.005 %w/w difenacoum only can be authorised by trained professional user because of the toxicological classification the use of PPE are mandatory. Given that, this legislation is national and in other Member States legislation could be different, each Competent Authority should consider that in order to grant the authorisation.

Physical, chemical and technical properties remain valid to the initial evaluation other than the stability test. No long-term stability test has been submitted; therefore a post-authorisation requirement should be included in the authorisation certificate.

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

According to Commission Regulation (EU) 2016/1179 the product RATOTER RATONICIDA, with the active substance difenacoum, at a level of 0.005% w/w is classified as REPRODUCTIVE TOXICITY CATEGORY 1B; H360D and SPECIFIC TARGET ORGAN TOXICITY AFTER REPEATED EXPOSURE. CATEGORY 2 (STOT RE 2); H373 May cause damage to organs (blood) through prolonged or repeated exposure

In the initial evaluation for authorisation of RATOTER RATONICIDA (conducted in 2013) concluded, in the absence of access to the study data underlying the EU Endpoint values, a default value of 10% was appropriate. After re-assessment we concluded the final value of 3% for dermal absorption in the case of grain and pellet, in formulations with difenacoum, data was already collected in the assessment

report of the active substance for a grain formulation. So we consider this more refined and approximate value for re-evaluation.

The conclusion for the risk assessment for the environment remains valid.

Therefore, RATOTER RATONICIDA is granted as a rodenticide product against house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*). It is to be used indoor and outdoor around buildings by trained professional. It is a ready to used grain bait to be used in tamper-resistant bait stations.

According to the renewal of anticoagulant active substance for trained professional users the product may be authorised for use in covered and protected bait points other than tamper resistant bait stations or as a permanent treatments. The applicant has not submitted any additional information to include these application methods, so the ES CA does not authorise other use different to tamper resistant bait stations.

Please, note that this assessment report includes all uses assessed by ES CA, only as information for the concerned Member States.

Spanish CA only grants the uses of RATOTER RATONICIDA according to the table 5 included in this assessment report due to our national risk mitigation measures.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

RATOTER RATONICIDA

2.1.2 Manufacturer(s) of the product

Name of manufacturer	WILL KILL S.A
Address of manufacturer	C/ 4 DE NOVIEMEBRE 6 07011 PALMA DE MALLORCA Spain
Location of manufacturing sites	C/ 4 DE NOVIEMEBRE 6 07011 PALMA DE MALLORCA Spain

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

Active substance	Difenacoum
Name of manufacturer	ACTIVA S.L.R.
Address of manufacturer	VIA FELTRE 32 20132 MILANO Italy
Location of manufacturing sites	Dr. TEZZA S.R.L. VIA TRE PONTI 22 37050 SANTA MATIA 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	0,005
-	-	Non-active substance	-	-	-

- The product contains a bittering agent and a dye.

Information on the full composition is provided in the confidential annex

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 Candidate(s) for substitution

No candidate for substitution 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).

Now that the Biocidal Products Regulation 528/2012 entered into force, the following substance(s) was/were identified as candidate(s) for substitution upon this renewal:

Difenacoum does meet the exclusion criteria according to Article 5(1) BPR. Because the following exclusion criteria are met:

- toxic for reproduction category 1B
- persistent, bioaccumulative and toxic

And therefore, difenacoum does meet the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

2.2.4 Type of formulation

Ready-to-use bait: grain

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

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Reproductive toxicity; Repr. 1B	H360D May damage the unborn child
Specific target organ toxicity after repeated exposure. Category 2	H373 May causes damage to organs (blood) through prolonged or repeated exposure

Table 3

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS08	
Signal word	-	Danger
Hazard statements	H360D	May damage the unborn child
	H373	May causes damage to organs (blood) through prolonged or repeated exposure
Supplemental hazard information	-	-
Supplemental label elements	-	
PPrecautionary statements	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P260	Do not breathe dust.
	P280	Wear protective gloves/ protective clothing/ eye protection/ face protection
	P314	Get medical advice/attention if you feel unwell.
	P405	Store locked up.

	P501	Dispose of contents and/or container as a hazardous waste to a registered establishment or undertaking, in accordance with current regulations.

2.4 Use(s) appropriate for <u>further</u> authorisation

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

Table 4

Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain)		**Use(s) appropriate for further authorisation**	
1	House mice and/or rats –general public – indoor	1	House mice and/or brown rats – trained professionals – indoor
2	House mice and/or rats – professional– indoor	2	Mice and/or brown rats – trained professionals – outdoor around buildings
3	House mice and/or rats –trained professional– indoor	-	-

Uses authorized in Spain according national Risk Mitigation Measures

Table 5

Use(s) considered appropriate for authorisation after former assessment (uses currently <u>under authorisation in Spain</u>)	**Use(s) appropriate for authorisation in Spain according national Risk Mitigation Measures.**
House mice and/or rats – general public – indoor	House mice and/or brown rats – trained professionals – indoor
House mice and/or rats – professional – indoor	Brown rats – trained professionals – outdoor around buildings
House mice and/or rats – trained professional – indoor	-

2.4.1 Use 1 – 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)	*Mus musculus* (house mice). *Rattus norvegicus* (brown rat).
Field(s) of use	Indoor.

Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	**Rats:** bait boxes with 200 g per baiting point **Mice:** bait boxes with 50 g 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 40kg Grams/kg of bait per packed bag: sachets of 25 g. Packaging material: sachets in plastic HDPE, cartoon cardboards, paper sacs

2.4.1.1 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.

2.4.1.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign

- 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 places that are not accessible to children or non-target animals.

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

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

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 – House mice and/or brown rats – trained professionals – Outdoor around building

Product Type(s)	14.
Where relevant, an exact description of the use	Not relevant for rodenticides.
Target organism(s) (including development stage)	*Mus musculus* (house mice). *Rattus norvegicus* (brown rat).
Field(s) of use	Outdoor around building
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	**Rats:** bait boxes with 200 g per baiting point **Mice:** bait boxes with 50 g 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 40kg Grams/kg of bait per packed bag: sachets of 25 g. Packaging material: sachets in plastic HDPE, cartoon cardboards, paper sacs

2.4.2.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the baiting points in area 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
- Follow any additional instructions provided by the relevant code of best practice.

2.4.2.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign
- 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.
- Do not apply this product directly in the burrows.

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

- 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.

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

See section 2.5.4

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 2.5.5

2.5 General directions for use

2.5.1 Instructions for use

- 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 of the SPC 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

- 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 is 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: 2 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.

Post-authorisation requirements: - Long-term stability test within 2 years

3 Assessment of the product

3.1 Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain)

3.1.1 Use 1 – House mice and/or brown rats – general public - indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticide
Target organism(s) (including development stage)	Brown rat (*Rattus norvegicus*) House mice (Mus musculus)
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**: 200g of bait per bait station. **Mice**: 50 g of bait per bait station.
Category(ies) of users	General public
Pack sizes and packaging material	Sachets of 25g in boxes of 800g.

3.1.2 Use 2 – House mice and/or brown rats – professional - indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rat (*Rattus norvegicus*) House mice (*Mus musculus*)
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**: Baits of 200g should be placed each 10m **Mice**: Baits of 50g should be placed each 5m
Category(ies) of users	Prefessionals
Pack sizes and packaging material	Sachets of 25g in boxes of 800g.

3.1.3 Use 3 – House mice and/or brown rats – trained professional - indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rat (*Rattus norvegicus*) House mice (*Mus musculus*)
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**: Baits of 200g should be placed each 10m **Mice**: Baits of 50g should be placed each 5m
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Sachets of 20, 25 and 50g in boxes of 800g.

3.2 Physical, chemical and technical properties

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>Guidance on Data Requirements for Active Substances and Biocidal Products</td><td>0.005</td><td>Nowadays the study is ongoing and the final results will be provided in March 2020.
However, in order to prove the stability of the product the applicant has done a READ ACROSS of Agrorat Dife-5, which is stable because the difference between the initial and final concentration after storage do not differ more than ±5%</td><td>IUCLID 3.4.1</td></tr>
<tr><td>Particle size distribution and dry sieve</td><td>CIPAC MT187 and CIPAC MT 170</td><td>0.005</td><td>These two properties are studied in parallel with the long term stability test of Agrorat Dife-3; therefore, the results will be provided as soon as the stability test finishes.</td><td>IUCLID 3.5</td></tr>
<tr><td>Attrition resistance of granules</td><td>CIPAC MT178</td><td>0.005</td><td>READ ACROSS Agrorat Dife-3
The product is sieved at 0.125 mm and since the seeds have an average size of 5x2 mm, the material passing through the 0.125 mm sieve consists only of the little amount of powder braked of seeds. Therefore, this amount of powder is insignificant compared to the whole weight of seeds</td><td>IUCLID 3.5</td></tr>
<tr><td>Dustiness</td><td>CIPAC MT 171</td><td>0.005</td><td>READ ACROSS Agrorat Dife-3
<table><tr><th>Initial value</th><th>Final value</th></tr><tr><td>1.4 mg (nearly dust-free)</td><td>1.7 mg (nearly dust-free)</td></tr></table></td><td>IUCLID 3.5</td></tr>
</table>

Apart from the properties mentioned above, which has been provided by the applicant through a letter of access of Laboratorios Agrochem S.L., 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.

The renewal is conditioned to the presentation of the long-term stability tests; therefore a post-authorisation condition should be showed in the authorisation certificate.

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.

Information on dermal absorption

	Re-assessment of the relevant data
Justification	In the initial evaluation for authorisation of 'Ratoter Ratonicida' (conducted in 2013) didn´t accept read across proposed by applicant and considered that due to the highly lipophilic nature of difenacoum (with a calculated log Kow of 7.62) and the relatively large size of the difenacoum molecule (with a molecular weight of 444.5) , a default value of 10% was appropriate. After re-assessment we concluded the final **value of 3%** for dermal absorption in the case of **grain and pellet**, in formulations with **difenacoum**, data was already collected in the assessment report of the active substance for a pellet formulation. So we consider this more refined and approximate value for re-evaluation.

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.

It has considered data about loose grain because RATOTER RATONICIDA is grain packaged in sachets.

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

The most relevant routes of exposure are the following:

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure** **Description of scenario**	**Exposed group**
1.	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.	Trained professional users,
2.	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.	Trained professional users,
3.	Touching unprotected bait	Secondary exposure: accidentally touched of unprotected bait. Indirect exposure, especially of children may happen. Two different scenarios of secondary exposure are available, the “handling of dead rodents” scenario and the “transient mouthing of poison bait” scenario. The first is excluded from the risk assessment due to unrealistic assumptions. For the latter, 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)**

Scenario [1] – Loading and placing bait boxes

Description of Scenario [1] - *Trained professional*		
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	0.005%
	Dermal absorption:	3%
	Operator body weight:	60 kg
	Amount of exposure to product during loading:	2.04 mg b.p (75th percentile for more than 4 manipulations)
	Number of manipulations during loading:	63
Tier 2	PEE (gloves)	5%

Calculations for Scenario [1]

Summary table: estimated exposure trained from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1 / No PPE	-	3.21×10^{-6} mg/kg bw/day	-	3.21×10^{-6} mg/kg bw/day
Scenario [1]	Tier 2 / PPE(gloves)	-	1.61×10^{-7} mg/kg bw/day	-	1.61×10^{-7} mg/kg bw/day

Scenario [2] – Cleaning

Description of Scenario [2] - *Trained professional*		
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	0.005%
	Dermal absorption:	3%

Description of Scenario [2] - *Trained professional*		
	Operator body weight:	60 kg
	Amount of exposure to product during cleaning:	3,79 mg b.p (75th percentile for more than 4 manipulations)
	Number of manipulations during cleaning:	16
Tier 2	PEE (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	-	1.51×10^{-6} mg/kg bw/day	-	1.51×10^{-6} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	7.58×10^{-8} mg/kg bw/day	-	7.58×10^{-8} mg/kg bw/day

Combine scenario for trained professional user

Summary table: estimated exposure from trained professional uses				
Exposure scenario	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1+2] Tier 1	-	4.72×10^{-6} mg/kg bw/day	-	4.72×10^{-6} mg/kg bw/day
Scenario [1+2] Tier 2	-	2.36×10^{-7} mg/kg bw/day	-	2.36×10^{-7} mg/kg bw/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]		
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 thereforethe potential exposure due to dermal contact with poisoned rodents is not included in the risk assessment because the available scenarios are unrealistic. For oral exposure of infants/children (toodler) two sub-scenarios are made: (3.a) one for toodler with 10 mg bait (default value for bait treated with repellent) and (3.b) one for toodler with 5 grams (TNsG on Human Exposure to Biocidal Products, User Guidance). Trained professional users should dispose unused or part-consumed products. Bait stations protect the product and should prevent access by infants (worse-case).		
	Parameters	Value
Tier 1	Infants Body weight	10 kg
	A.S. content of BP	0.005%
	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.a]	Tier 1 / No PPE	-	-	5×10^{-5} mg/kg bw/d	5×10^{-5} mg/kg bw/d
Scenario [3.b]		-	-	0.025 mg/kg bw/d	0.025 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.

Dietary exposure

Exposure to residues in food is not assessed because no contamination of food or feeding stuff is

foreseen.

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

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

Aggregated exposure

No aggregated exposure is foreseable 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 (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.	Trained-professional	Tier 2 / PPE	1.61 x 10^{-7} mg/kg bw/day
1.	Trained-professional	Tier 1/ no PPE (unrealistic)	3.12 x 10^{-6} mg/kg bw/day
2.	Trained-professional	Tier 2/ PPE	7.58 x 10^{-8} mg/kg bw/day
2.	Trained-professional	Tier 1/ no PPE (unrealistic)	1.516 x 10^{-6} mg/kg bw/day
3.a	Bystander (toodler)	No PPE	5 x 10^{-5} mg/kg bw/d
3.b	Bystander (toodler)	No PPE	0.025 mg/kg bw/d

3.6.4 Risk characterisation for human health

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 x 10^{-6}
$AEL_{medium-term}$	-	0.00034		-	1.1 x 10^{-6}
$AEL_{long-term}$	-	0.00034		-	1.1 x 10^{-6}
ARfD	Not applicable	-	Not applicable	-	Not applicable
ADI	Not applicable	-	Not applicable	-	Not applicable

Risk for professional users

Risk for trained professional users

Systemic effects

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}	3.12×10^{-6}	292	No
	Tier 2			1.61×10^{-7}	15	Yes
Cleaning / Scenario [2]	Tier 1			1.516×10^{-6}	138	No
	Tier 2			7.58×10^{-8}	7	Yes
Scenario [1] + [2]	Tier 1	0.00034	1.1×10^{-6}	4.72×10^{-6}	430	No
Scenario [1] + [2]	Tier 2	0.00034	1.1×10^{-6}	2.36×10^{-7}	21	Yes

Local effects
There is no need to consider local effects separately.

Conclusion

The exposure assessment for trained professional pest control operators under reasonable worst case assumptions (63 loadings and 16 clean-ups/day), yielded a potential dermal exposure leading to a systemic dose of 4.72×10^{-6} mg/kg/day for an unprotected operator during bait handling operations. Comparison to the LOAEL of 0.001 mg/kg/day (based on a teratogenicity test in rabbits) shows that the use of rodenticide baits containing 0.005% difenacoum causes a potential health risk for pest control operators not wearing appropriate PPE (gloves), as indicated by the resulting margin of exposure.

Nevertheless, since pest control operators are supposed to wear protective gloves during pest control operations, a refined assessment is conducted. The resulting margin of exposure indicates that the use of rodenticide baits containing 0.005% difenacoum does not cause a risk for pest control operators if gloves are worn.

The result of the risk assessment concerning use of difenacoum in RATOTER RATONICIDA indicates that the acceptable exposure level is not exceeded for trained professionals (pest control operators) with gloves. Exposure during manufacture of the active substance' and formulation of products is beyond the scope of BPD and therefore has not been addressed.

Risk for the general public

Adults or children may be present following application and may be incidentally exposed by touching unprotected bait under a 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.

Toodler 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)
Toodler may ingest part of the bait / [3.a]	Tier 1- (no PPE)	0.00034	1.1×10^{-6}	0.025	22.7×10^{6}	No
Toodler may ingest part of the bait / [3.b]				5×10^{-5}	4545	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 4545 % of AEL based on a default exposure value which assumes that infants might ingest 10 mg of poison bait and 2.2×10^{6} % of AEL when assuming that children might ingest 5 g bait. These values show that infants and children (toodler) 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.

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 remains valid.

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

There is only one substance of concern in the formulates, so this risk has not been considered

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.	Trained professional user	Tier 1/ no PPE (unrealistic)	1.1 x 10^{-6}	3.21 x 10^{-6}	292	No
1.	Trained professional user	Tier 2/ PPE	1.1 x 10^{-6}	1.61 x 10^{-7}	15	No
2.	Trained professional user	Tier 1/ no PPE (unrealistic)	1.1 x 10^{-6}	1.51 x 10^{-6}	138	Yes
2.	Trained professional user	Tier 2/ PPE	1.1 x 10^{-6}	7.58 x 10^{-8}	7	Yes
3.	General public (Children)	Tier 1 (without efficient bitter agent)	1.1 x 10^{-6}	0.025	22.7x10^{5}	No
3.	General public (Children)	Tier 2 (with bitter agent)	1.1 x 10^{-6}	5 x 10^{-5}	4545	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. Accordingly, the conclusion from the former assessment regarding the environment remains valid.

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 opinion 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 Opinion 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.