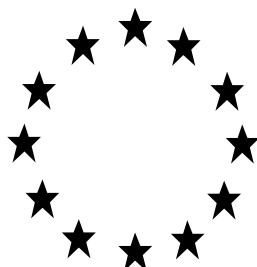


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



Product identifier in R4BP	Raticruz Ratas
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Difenacoum
Case No. in R4BP	BC-GP000069-40
Asset No. in R4BP	ES-0000212-0000
Evaluating Competent Authority	SPAIN
Internal registration/file no	ES/APP(NA)-2018-14-00102
Date	February 2018.

Table of content

1	Conclusion	3
2	Summary of the product assessment	4
2.1	Administrative information	4
2.2	Composition and formulation.....	4
2.3	Classification and Labelling according to the Regulation (EC) No 1272/2008.....	5
2.4	Use(s) appropriate for further authorisation	7
2.5	General directions for use	12
3	Assessment of the product	15
3.1	Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain).....	15
3.2	Physical, chemical and technical properties.....	17
3.3	Physical hazards and respective characteristics.....	17
3.4	Methods for detection and identification.....	18
3.5	Efficacy against target organisms	18
3.6	Risk assessment for human health	20
3.7	Risk assessment for animal health.....	22
3.8	Risk assessment for the environment	22
3.9	Assessment of a combination of biocidal products	22
3.10	Comparative assessment	22
4	Confidential annex (Access level: “Restricted” to applicant and authority).....	24
4.1	Full composition of the product	24
4.2	List of studies for the biocidal product (Confidential data)	25

1 Conclusion

The assessment presented in this report has shown that the ready-to-use product, RATICRUZ RATAS, 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 RATICRUZ RATAS 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. An accelerated stability test has been submitted. However, 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.

Therefore, RATICRUZ RATAS is granted 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 by trained professional. It is a ready to used block 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.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

RATICRUZ RATAS

2.1.2 Manufacturer(s) of the product

Name of manufacturer	WILL KILL SA
Address of manufacturer	C/4 de noviembre 6 – Palma de Mallorca
Location of manufacturing sites	c/4 de noviembre 6 – Palma de Mallorca

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	Via Feltre, 32 20132 Milano Italia
Location of manufacturing sites	Dr Tezza s.r.l Via Tre Ponti 22 37050 S. Maria di Zevio (VR) - Italia

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 (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 Candidate 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: block

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 — repeated exposure; STOT RE 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	-	
Precautionary statements	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P280	Wear protective gloves.
	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.
Note	-	

2.4 Uses 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

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

2.4.1 Use 1- Mice and/or brown rats – trained professionals – indoor

Product Type	14
Where relevant, an exact description of the use	Not relevant for rodenticides.
Target organisms (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat)
Field of use	Indoor
Application method	Ready-to-use bait to be used in tamper-resistant bait stations
Application rates and frequency	Mice: 40-50 g of bait per baiting point Rats: 100-200 g of bait per baiting point
Category of users	Trained professional
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 24Kg Grams/kg of bait per packed bag: blocks of 20g, 50g and 100g. Packaging material: The blocks are supplied inside cartoon boxes and plastic PVC trays.

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 [in accordance with the applicable code of good practice, if any].
- 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.

2.4.1.3 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 - 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 rat)
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	Mice: 40-50 g of bait per baiting point Rats: 100-200 g of bait per baiting point
Category(ies) of users	Trained professionals
Pack sizes and packaging material ¹	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 24Kg Grams/kg of bait per packed bag: blocks of 20g, 50g and 100 g. Packaging material: The blocks are supplied inside cartoon boxes and plastic PVC trays.

2.4.2.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period
- 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 [*in accordance with the applicable code of good practice, if any*].
- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of

rodent activities.

- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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.

2.4.3 Use 3 – Brown rats – trained professionals – Outdoor open areas & waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	<i>Rattus norvegicus</i> (brown rat)
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: 100-200 g of bait per baiting point
Category of user	Trained professionals

Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Number of packed bags per packaging: up to 24Kg</p> <p>Grams/kg of bait per packed bag: blocks of 20g, 50g and 100 g</p> <p>Packaging material: The blocks are supplied inside cartoon boxes and plastic PVC trays.</p>
-----------------------------------	--

2.4.3.1 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
- Follow any additional instructions provided by the relevant code of best practice.

2.4.3.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- 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.

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

- 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.

2.4.3.4 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.

2.5 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 2.itle: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.

2.5.2 Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign [in accordance with the applicable code of good practice, if any]".
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").
- 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 [unless authorised for permanent baiting treatments].
- 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, 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].

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.

2.6 Other information

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

Post-authorisation requirements:

- Long-term stability test within 2 years

3 Assessment of the product

3.1 Uses 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 and outdoor around buildings.

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat)
Field(s) of use	Indoor Outdoor around buildings
Application method(s)	The biocidal product is ready to use block bait in bait stations.
Application rate(s) and frequency	Mice: 40- 50gr of bait per baiting point Rats: 100-200gr of bait per baiting point
Category(ies) of users	General public
Pack sizes and packaging material	Grams/kg of bait per packed bag: blocks of 20g, 50g and 100 g. Packaging material: The blocks are supplied inside cartoon boxes and plastic PVC trays.

3.1.2 Use 2 – House mice and/or brown rats – professional– indoor and outdoor around buildings.

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat)
Field(s) of use	Indoor Outdoor around buildings.
Application method(s)	The biocidal product is ready to use block bait in bait stations.

Application rate(s) and frequency	Mice: 50gr of bait per baiting point Rats: 200gr of bait per baiting point
Category(ies) of users	Trained professional.
Pack sizes and packaging material	Grams/kg of bait per packed bag: blocks of 20g, 50g and 100 g Packaging material: The blocks are supplied inside cartoon boxes and plastic PVC trays.

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

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat)
Field(s) of use	Indoor Outdoor around buildings Open areas Waste dumps.
Application method(s)	The biocidal product is ready to use block bait in bait stations.
Application rate(s) and frequency	Mice: 50gr of bait per baiting point Rats: 200gr of bait per baiting point
Category(ies) of users	Trained professional.
Pack sizes and packaging material	Grams/kg of bait per packed bag: blocks of 20g, 50g and 100 g Packaging material: The blocks are supplied inside cartoon boxes and plastic PVC trays.

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	0.005	Difenacoum active ingredient initial content: 0.0041 ± 0.0005 % w/w Difenacoum active ingredient final content: 0.0037 ± 0.0003 % w/w Δ[C] = -9.76% The result complies with the tolerance value (-10%). READ ACROSS (Ratonex H)	IUCLID 3.4.1
Storage stability test – long term storage at ambient temperature	Guidance on Data Requirements for Active Substances and Biocidal Products	0.005	Study ongoing Final results: October 2019	IUCLID 3.4.1

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.

The renewal is conditioned to the presentation of the long term stability test; 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

Parameters	Result	Reference
Analytical method	HPLC	IUCLID 5
Linearity	Range of work: 0.05 mg/L to 0.5 mg/L $R^2 = 0.9979$	
Recovery	94.54%	
Precision	17.26 % (<20%)	

Apart from the parameters presented 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 methods for detection and identification remains valid.

3.5 Efficacy against target organisms

Taking into account that a complete efficacy data package with 0.005% w/w difenacoum was submitted it is assumed that the level of palatability remains the same being at least 20% of palatability in laboratory tests.

The applicant has submitted two new studies in order to support the efficacy in field conditions against *Rattus norvegicus* and *Mus musculus*. These studies were carried out at a concentration of 0.0026% w/w difenacoum, which is considered a worse case, and thus demonstrating the efficacy of the biocidal at 0.005% w/w difenacoum product given that the change in the content of co-formulants it is considered minimum and therefore it is not affected to the efficacy of the product. Please, see the summary of field trials submitted by the applicant.

In conclusion, according to the test provided, ES CA consider that the biocidal product with 0.005 % w/w difenacoum is effective against rats and mice indoor and outdoor.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Field of use envisaged	Test substance	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Rodenticide	Field test (Indoor)	Difenacoum 0.0026% w/w	House mouse (<i>Mus musculus</i>)	Field test. According The guidance on the BPR Volume II Efficacy, assessment and evaluation, parts B + C and Transitional Guidance for PT 14	The trial was set up in a ship animal feed storage The test included the phases: pre-treatment census, pre-treatment lag, treatment census, post-treatment lag, post treatment census. 40g were placed inside bait stations each 5 m.	Efficacy = 100 % Percentage of bait consumed after the control operation compared to the amount of bait consumed before the control operation is $\leq 10\%$ (according TNG for PT 14)	IUCLID 13
Rodenticide	Field test: (Indoor/ Outdoor)	Difenacoum 0.0026% w/w	Brown rat (<i>Rattus norvegicus</i>)	Field test. According The guidance on the BPR Volume II Efficacy, assessment and evaluation, parts B + C and Transitional Guidance for PT 14	The trial was set up in a ship animal feed factory The test included the phases: pre-treatment census, pre-treatment lag, treatment census, post-treatment lag, post treatment census. 100g were placed inside bait stations each 5 m.	Efficacy = 100 % Percentage of bait consumed after the control operation compared to the amount of bait consumed before the control operation is $\leq 10\%$ (according TNG for PT 14)	IUCLID 13

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

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.

Given that RATICRUZ RATAS classifies as Repr1B H360D and STOT RE 2 H373, the use of gloves is mandatory (P280). Therefore, the exposure assessment for non-trained professional user is covered by the trained professional because it should be noted that the number of manipulation of non-trained professional user is lower than trained professional. In this sense the exposure assessment for trained professional is a worse case.

Nevertheless, according our national rules, the non-trained professional user (for example, livestock farmers) is extrapolated to general public (non-professional user). Therefore, in Spain RATICRUZ RATAS (difenacoum 0.005%) will not be authorised for non-trained professional user.

3.6.4 Risk characterisation for 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.

3.6.4.1 Risk for trained professional users

The conclusion from the former assessment regarding the risk characterisation for trained professional user remains valid.

3.6.4.2 Risk for professional users

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.

Given that RATICRUZ RATAS classifies as Repr1B H360D and STOT RE 2 H373, the use of gloves is mandatory (P280). Therefore, the exposure assessment for non-trained professional user is covered by the trained professional because it should be noted that the number of manipulation of non-trained professional user is lower than trained professional. In this sense the exposure assessment for trained professional is a worse case.

Nevertheless, according our national rules, the non-trained professional user (for example, livestock farmers) is extrapolated to general public (non-professional user). Therefore, in Spain RATICRUZ RATAS (difenacoum 0.005%) will not be authorised for non-trained professional user.

3.6.4.3 Risk for the general public

According to 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, the biocidal product containing anticoagulant active substance cannot be authorised by general public if the concentration in the biocidal product is above the specific limit concentration ($\geq 0.003\%$).

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

The biocidal product does not contain other substances in quantities that would be of toxicological concern in the production formulation.

3.6.4.6 Summary of risk characterisation

The conclusion from the former assessment regarding risk characterisation remains valid, except to the authorisation for general public and professional user which have been removed to the authorisation in

order to comply with the requirements laid down in 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.

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 including the groundwater risk assessment.

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 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.