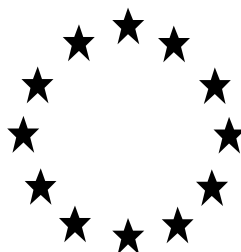


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL
PRODUCT FOR THE MINOR CHANGE OF A
NATIONAL AUTHORISATION**



Product identifier in R4BP	CHEMRAT DIFE-3
Product type(s):	14 (Rodenticide)
Active ingredient(s):	DIFENACOUM
Case No. in R4BP	BC-UP054182-22 (NA-MIC)
Asset No. in R4BP	ES-0019310-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/BB(NA)-2018-14-00510
Date	August 2018 (updated: June 2020)

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4.	Confidential annex (Access level: “Restricted” to applicant and authority). ¡Error! Marcador no definido.	

Application type	Ref MS	Case number/Asset number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-BBS	ES	BC-MV040236-19 ES-0019310-0000	September 2018	Authorisation of same biocidal product
NA-MIC	ES	BC-UP054182-22 ES-0019310-0000	June 2020	Post-authorization: Results long term stability test

1 Conclusion

The assessment presented in this report includes the minor change submitted by the applicant.

It is concluded that the ready-to-use product, CHEMRAT DIFE-3, with the active substance difenacoum, at a level of 0.0029% w/w, may be authorised for use as a rodenticide (product-type 14). This product is a same biocidal product (BB) of AGRORAT DIFE-3 (ES-0000105-0000). Now a NA-MIC has been submitted and a PAR has been done.

Regarding physical and chemical properties and efficacy the conclusions are the same as the product AGRORAT DIFE-3

According to Commission Regulation (EU) 2016/1179 the product AGRORAT DIFE-3, 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.

The risk assessment for the environment has been performed for the intended uses, indoor, outdoor around buildings, outdoor open areas and waste dumps since the concentration of the active substance has been reduced. The new evaluation shows that the conclusions for the first evaluation remain valid.

Therefore, CHEMRAT DIFE-3 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. It is a ready to used bait to be used in tamper-resistant bait stations.

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

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

Spanish CA only grants the use of CHEMRAT DIFE-3 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

CHEMRAT DIFE-3

2.1.2 Manufacturer(s) of the product

Name of manufacturer	LABORATORIOS AGROCHEM S.L.
Address of manufacturer	C/ Tres Rieres, 10 08292 - Esparreguera (Barcelona) SPAIN
Location of manufacturing sites	C/ Tres Rieres, 10 08292 - Esparreguera (Barcelona) SPAIN

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

Active substance	DIFENACOUM
Name of manufacturer	ACTIVA 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 **¡Error! No se encuentra el origen de la referencia.**).
- 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 and very 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
Specific target organ toxicity after repeated exposure. Category 2	H373 May cause damage to organs (blood) through prolonged or repeated exposure

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.
	P260	Do not breathe dust/fume/ gas/mist/vapours/spray
	P280	Wear protective gloves.
	P314	Get medical advice/attention if you feel unwell.
	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– indoor	1	House mice and Brown rats – general public - indoor
		2	Brown Rats – general public – outdoor around buildings
2	House mice and/or brown rats – professionals – indoor	3	House mice – professionals - indoor
		4	Brown Rats – professionals - indoor
		5	House mice and/or Brown rats – Professionals – outdoor around buildings
3	House mice and/or brown rats – trained professionals – indoor	6	House mice and/or Brown rats – trained professionals - indoor
		7	House mice and/or Brown rats – trained professionals – outdoor around buildings
		8	Brown Rats – trained professionals – outdoor open areas & waste dumps

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 brown rats – general public– indoor	House mice and Brown rats – general public - indoor
	Brown Rats – general public – outdoor around buildings
House mice and/or brown rats – professionals – indoors	House mice – professionals - indoor
	Brown Rats – professionals - indoor
	Brown Rats – professionals – outdoor around buildings
House mice and/or brown rats – trained professionals – indoors	House mice and/or Brown rats – trained professionals - indoor
	Brown rats – trained professionals – outdoor around buildings

2.4.1 Use 1– House mice and brown rats– general public – indoor

Product Type(s)	14
Where relevant, an exact	Not relevant for rodenticides

description of the use	
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	Mice: bait boxes with 60g of product each 5-10m 60g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10m (5m in case of strong infestation and 10m in case of weak infestation). Rats: bait boxes with 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	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 from 10g to 100g. Packaging material: Bags, sacks, Buckets, Tubes, Bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE or HDPE or PVC

2.4.1.1. Use-specific instructions for use

- The bait stations should be visited [for mice - at least every 2 to 3 days at] [for rats - 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.

2.4.1.2. 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

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

- See section 5.5

2.4.2. Use 2 - Brown Rats – general public – 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)	<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: bait boxes with 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	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 from 10g to 100g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC.

2.4.2.1. 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.

2.4.2.2. Use-specific risk mitigation measures

- See section 2.5.2

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 2.5.3

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- 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, in sachets or as loose grain
Application rate(s) and frequency	Mice: bait boxes with 60g of product each 5-10m 60g 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	<p>Minimum pack size of 3 kg.</p> <p>Number of packed bags per packaging: up to 30 kg. Grams/kg of bait per packed bag: individual sachets from 10g to 60g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC.</p> <p>Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.</p>

2.4.3.1 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.

2.4.3.2 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

- When placing bait stations close to 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

2.4.4. Use 4 – 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, in sachets or as loose grain
Application rate(s) and frequency	Rat: bait boxes with 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 30 kg. Grams/kg of bait per packed bag: individual nonwoven sachets from 10g to 100g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC. Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

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

2.4.5 Use 5 – 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, in sachets or as loose grain
Application rate(s) and frequency	Rats: bait boxes with 100 g 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).

	<p>Mice: bait boxes with 60g of product each 5-10m.</p> <p>60g 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).</p>
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 30 kg. Grams/kg of bait per packed bag: individual sachets from 10g to 100g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC.</p> <p>Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.</p>

2.4.5.1 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.

2.4.5.2 Use-specific risk mitigation measures

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

2.4.5.3 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.

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

See section 2.5.4

2.4.5.5 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 – 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, in sachets or as loose grain
Application rate(s) and frequency	Rats: bait boxes with 100-200 g per baiting point Mice: bait boxes with 60-80 g per baiting point Not relevant in ES]: Permanent baiting
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 30 kg. Grams/kg of bait per packed bag: individual sachets from 10g to 200g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

2.4.6.1 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.

[Not relevant in ES]:

Additional specific instruction of use for permanent baiting:

- Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

2.4.6.2 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 [unless authorised for permanent baiting treatments].
- This product shall only be used indoors and in places that are not accessible to children or non-target animals.

[Not relevant in ES]:

Additional specific risk mitigation measures for permanent baiting:

- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.
- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

- When placing bait points close to 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 2.5.4.

2.4.7 Use 7 – 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, in sachets or as loose grain. Direct application of ready-to-use bait into burrows.
Application rate(s) and frequency	Rats: bait boxes with 100-200 g per baiting point Mice: bait boxes with 60-80 g per baiting point Burrow: 200 g of bait per burrow only inside of tamper resistant baiting stations Not relevant in ES]: Permanent baiting
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 30 kg. Grams/kg of bait per packed bag: individual sachets from 10g to 200g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. . In this case, the maximum pack size is 10kg.

2.4.7.1 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 (except when directly applied to burrows inside of tamper resistant baiting stations).
- Baits must be placed to minimise the exposure to non-target species and children.
- Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- Follow any additional instructions provided by the relevant code of best practice.

[Not relevant in ES]:

Additional specific instruction of use for permanent baiting:

- Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.
- *[When available]* 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 (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 [unless authorised for permanent baiting treatments].
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

[Not relevant in ES]:

Additional specific risk mitigation measures for permanent baiting:

- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.
- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

2.4.7.4 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 – 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, in sachets or as loose grain. Direct application of ready-to-use bait into burrows.
Application rate(s) and frequency	Rats: bait boxes with 100-200 g per baiting point Burrow: 200 g of bait per burrow only inside of tamper resistant baiting stations. Not relevant in ES]: Permanent baiting
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 30 kg. Grams/kg of bait per packed bag: individual sachets from 10g to 200g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

2.4.8.1 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 (except when directly applied to burrows inside of tamper resistant baiting stations).
- Baits must be placed to minimise the exposure to non-target species and children.
- Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- Follow any additional instructions provided by the relevant code of best practice.

[Not relevant in ES]:

Additional specific instruction of use for permanent baiting:

- Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.
- *[When available]* 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
- 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 [unless authorised for permanent baiting treatments].
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

[Not relevant in ES]:

Additional specific risk mitigation measures for permanent baiting:

- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.
- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

2.5 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.
- 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 2.5.3 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 that 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.
- Bait in sachets: Do not open the sachets containing the bait.
- Loose grains: Place the bait in the bait station by using a dosage device. Specify the methods to minimise dust (e.g. wet wiping)

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 2.5.3 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.
- Bait in sachets: Do not open the sachets containing the bait
- Loose grains: Place the bait in the bait station by using a dosage devise. Specify the methods to minimise dust (e.g. wet wiping)

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 2.5.3 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 2.5.3 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.

2.5.1 2.5.4 Instructions for safe disposal of the product and its packaging

- At the end of the treatment, dispose 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: 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.

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– indoor

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 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	Mice: 2 bait stations with 50g each 10 m ² Rats: 3-5 bait stations with 200g each 10 m ²
Category(ies) of users	General public
Pack sizes and packaging material	Individual sachets of 25 and 50g in containers of 200g, 250g, 500g and 1kg Material: PE or PP or Carton box or HDPE or PE

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)	<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	Mice: 2 bait stations with 50g each 10 m ² Rats: 3-5 bait stations with 200g each 10 m ²
Category(ies) of users	Professional
Pack sizes and packaging material	Individual sachets of 25 and 50g in containers of 200g, 250g, 500g and 1kg Material: PE or PP or Carton box or HDPE or PE

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)	<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	Mice: 2 bait stations with 50g each 10 m ² Rats: 3-5 bait stations with 200g each 10 m ²
Category(ies) of users	Trained Professional
Pack sizes and packaging material	Individual sachets of 25 and 50g in containers of 500g, 5kg and 10kg Material: PE or PP or Carton box or HDPE or PE

3.2. *Physical, chemical and technical properties*

See AGRORAT DIFE-3 physical, chemical and technical properties evaluation.

3.3. *Physical hazards and respective characteristics*

See AGRORAT DIFE-3 physical hazards evaluation.

3.4. *Methods for detection and identification*

See AGRORAT DIFE-3 analytical methods evaluation.

3.5. *Efficacy against target organisms*

See AGRORAT DIFE-3 efficacy evaluation.

3.6. *Risk assessment for human health*

3.6.1. Assessment of effects of the active substance on human health

See AGRORAT DIFE-3 Risk assessment for human health evaluation.

3.6.2. Assessment of effects of the product on human health

See AGRORAT DIFE-3 Risk assessment for human health evaluation.

3.6.3. Exposure assessment

See AGRORAT DIFE-3 Exposure assessment evaluation

3.6.4. Risk characterization for human health

See AGRORAT DIFE-3 Risk characterisation for human health evaluation

3.7. Risk assessment for animal health

See AGRORAT DIFE-3 Risk assessment for animal health evaluation.

3.8. Risk assessment for the environment

See AGRORAT DIFE-3 Risk assessment for the environment evaluation.

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.