## **ANNEX**

## SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

## RATIGEN SECURE FRESH BAIT

**Product type(s)** 

PT14: Rodenticides

**Authorisation number:** 2022-11-02-B01

**R4BP asset number:** MT-0029607-0000

## 1. ADMINISTRATIVE INFORMATION

## 1.1. Trade name(s) of the product

Trade name(s) RATIGEN SECURE FRESH BAIT
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## 1.2. Authorisation holder

	Name	IMPEX EUROPA, S.L.
Name and address of the authorisation holder	Address	Avda. de Pontevedra, nº 39 36600 Vilagarcía de Arousa Spain
Authorisation number		2022-11-02-B01
R4BP asset number		MT-0029607-0000
Date of the authorisation		05/02/2014
Expiry date of the authorisation		31/12/2025

## 1.3. Manufacturer(s) of the product

Name of manufacturer	IMPEX EUROPA, S.L.
Address of manufacturer	Avda. de Pontevedra, nº 39 36600 Vilagarcía de Arousa Spain
Location of manufacturing sites	Polígono Industrial Trabanca Badiña, parcelas 22-24 36600 Vilagarcía de Arousa Spain

## **1.4.** Manufacturer(s) of the active substance(s)

Active substance	Brodifacoum
Name of manufacturer	Activa S.r.1
Address of manufacturer	via Feltre, 32 20132 Milán Italy
Location of manufacturing sites	Tezza S.r.l, via Tre Ponti 22 37050 S. Maria di Zevio (VR) Italy

## 2. PRODUCT COMPOSITION AND FORMULATION

## 2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro -1-napthyl]-4-hydroxycoumarin	active substance	56073-10-0	259-980-5	0,0025

## **2.2.** Type(s) of formulation

Ready-to-use bait: fresh bait

## 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H373: May cause damage to organs (blood) through prolonged or repeated exposure
Precautionary statements	P102: Keep out of reach of children.  P308+P313: IF exposed or concerned: Get medical advice.  P501: Dispose of contents to and/or its container, as well as dead rodents, as hazardous waste in accordance with what is established by municipal ordinances. (General public and Professional).  P501: Dispose of contents to y/o su recipiente, así como los roedores muertos, a través de un gestor de
	residuos peligrosos autorizado, de acuerdo con la normativa vigente.( Profesional especializado).

## 4. AUTHORISED USE(S)

### 4.1. Use description

Table 1. Use #1 - Common Mice - General Public - Indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Common name: house mouse Development stage: -
Field(s) of use	indoor use
Application method(s)	Method: in bait boxes  Detailed description: Ready-to-use paste bait in tamper-resistant baits.
Application rate(s) and frequency	Application rate: 20-40 grams of bait per bait holder. If it is necessary to use more than one bait holder, the minimum distance between bait holders will be 5 meters.  Dilution (%): -  Number and timing of application:
Category(ies) of users  Pack sizes and packaging material	general public (non-professional)  Maximum pack size: Up to 50 g Number of bait boxes and/or refills per container: Up to 50 g. Grams of bait per bait holder and/or refills: 10-20 g of bait in bags. Packaging material: PE/Aluminium/Polyester

## 4.1.1. Use-specific instructions

Bait boxes should be checked at least every 2-3 days at the start of treatment and at least once a week thereafter to check for bait acceptance, intact bait boxes and to remove dead rodents. Reload the bait box when necessary. For the general public, the use of gloves is recommended. See general instructions for use

## 4.1.2. Use-specific risk mitigation measures

### 4.1.3. Use-specific risk mitigation measures

See general instructions for use

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

See general instructions for use

# 4.1.5. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

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

See general instructions for use

## 4.2. Use description

Table 2. Use #2 - Rats - General Public - Indoors

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: -
Field(s) of use	indoor use
Application method(s)	Method: in bait boxes  Detailed description: Ready-to-use paste bait in tamper-resistant baits.
Application rate(s) and frequency	Application rate: 100-200 grams of bait per bait holder. If it is necessary to use more than one bait holder, the minimum distance between bait holders will be 5 meters.  Dilution (%): -  Number and timing of application:

Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Maximum pack size: Up to 150 g Number of bait boxes and/or refills per container: Up to 150 g. Grams of bait per bait holder and/or refills: 10-20 g of bait in bags. Packaging material: PE/Aluminium/Polyester.

### 4.2.1. Use-specific instructions

Bait boxes should be checked 5-7 days after the start of treatment and at least once a week thereafter to check for bait acceptance, intact bait boxes, and removal of dead rodents. Reload the bait box when necessary. For the general public, the use of gloves is recommended. See general instructions for use

### **4.2.2.** Use-specific risk mitigation measures

### **4.2.3.** Use-specific risk mitigation measures

See general instructions for use

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

See general instructions for use

# 4.2.5. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

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

See general instructions for use

#### 4.3. Use description

Table 3. Use #3 – Rats – General Public – Around Buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the	Not relevant for rodenticides
authorised use	

Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: -
Field(s) of use	Otro
	around buildings
Application method(s)	Method: in bait boxes
	Detailed description: Ready-to-use paste bait in tamper-resistant baits.
Application rate(s) and frequency	Application rate: 100-200 grams of bait per bait holder. If it is necessary to use more than one bait holder, the minimum distance between bait holders will be 5 meters.
	Dilution (%): -
	Number and timing of application:
	_
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Maximum pack size: Up to 150 g Number of bait boxes and/or refills per container: Up to 150 g. Grams of bait per bait holder and/or refills: 10-20 g of bait in bags. Packaging material: PE/Aluminium/Polyester.

### 4.3.1. Use-specific instructions

Place the bait holder in areas not subject to flooding. Replace baits that have been water damaged or contaminated by dirt. Bait boxes should be checked 5-7 days after the start of treatment and at least once a week thereafter to check for bait acceptance, intact bait boxes, and removal of dead rodents. Reload the bait box when necessary. For the general public, the use of gloves is recommended. See general instructions for use

## 4.3.2. Use-specific risk mitigation measures

#### 4.3.3. Use-specific risk mitigation measures

See general instructions for use

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

See general instructions for use

# 4.3.5. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

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

See general instructions for use

## 4.4. Use description

Table 4. Use #4 - Common Mice - Professional - Indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)  Field(s) of use	Scientific name: Mus musculus Common name: house mouse Development stage: - indoor use
Application method(s)	Method: in bait boxes  Detailed description: Ready-to-use paste bait in tamper-resistant baits.
Application rate(s) and frequency	Application rate: 20-40 grams of bait per bait holder. If it is necessary to use more than one bait holder, the minimum distance between bait holders will be 5 meters.  Dilution (%): -  Number and timing of application:
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of individual bags per container: Up to 25 kg. Grams/kilogram of bait per bag: 10-20 g of bait in bags. Packaging material: PE/Aluminium/Polyester.

#### 4.4.1. Use-specific instructions

Bait boxes should be checked at least every 2-3 days at the start of treatment and at least once a week thereafter to check for bait acceptance, intact bait boxes and to remove dead rodents. Reload the bait box when necessary. Follow the additional instructions provided by the Good Practices Manual. See genera instructions for use

## 4.4.2. Use-specific risk mitigation measures

### 4.4.3. Use-specific risk mitigation measures

See general instructions for use

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

When bait boxes are placed near water drainage systems make sure the bait does not come into contact with water. See general instructions for use

# 4.4.5. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

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

See general instructions for use

### 4.5. Use description

Table 5. Use #5 - Rats - Professional - Indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: -
Field(s) of use	indoor use

	-
Application method(s)	Method: in bait boxes
	Detailed description: Ready-to-use paste bait in tamper-resistant baits.
Application rate(s) and frequency	Application rate: 100-200 grams of bait per bait holder. If it is necessary to use more than one bait holder, the minimum distance between bait holders will be 5 meters.  Dilution (%): -  Number and timing of application:
	-
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of individual bags per container: Up to 25 kg. Grams/kilogram of bait per bag: 10-20 g of bait in bags. Packaging material: PE/Aluminium/Polyester.

### **4.5.1.** Use-specific instructions

Bait boxes should be checked 5-7 days after the start of treatment and at least once a week thereafter to check for bait acceptance, intact bait boxes, and removal of dead rodents. Reload the bait box when necessary. Follow the additional instructions provided by the Good Practices Manual. See general instructions for use

### 4.5.2. Use-specific risk mitigation measures

#### 4.5.3. Use-specific risk mitigation measures

See general instructions for use

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

When bait boxes are placed near water drainage systems make sure the bait does not come into contact with water. See general instructions for use

# 4.5.5. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

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

See general instructions for use

## 4.6. Use description

Table 6. Use #6 - Rats - Professional - Around buildings.

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: -
Field(s) of use	Otro around buildings
Application method(s)	Method: in bait boxes  Detailed description: Ready-to-use paste bait in tamper-resistant baits.
Application rate(s) and frequency	Application rate: 100-200 grams of bait per bait holder. If it is necessary to use more than one bait holder, the minimum distance between bait holders will be 5 meters.  Dilution (%): -  Number and timing of application:
Category(ies) of users  Pack sizes and packaging material	professional  Minimum pack size of 3 kg. Number of individual bags per container: Up to 25 kg. Grams/kilogram of bait per bag: 10-20 g of bait in bags. Packaging material: PE/Aluminium/ Polyester.

### **4.6.1.** Use-specific instructions

Protect the baits from atmospheric conditions (eg: rain, snow, etc). Place the bait holder in areas not subject to flooding. Bait boxes should be checked 5-7 days after the start of treatment and at least once a week thereafter to check for bait acceptance, intact bait boxes, and removal of dead rodents. Reload the bait box when necessary. Replace baits that have been water damaged or contaminated by dirt. Follow the additional instructions provided by the Good Practices Manual. See general instructions for use

### **4.6.2.** Use-specific risk mitigation measures

#### **4.6.3.** Use-specific risk mitigation measures

Do not apply the product directly in burrows. See general instructions for use

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

When bait boxes are placed near surface water (eg rivers, lakes, water channels, dams, irrigation canal/ditch) or water drainage systems ensure that the bait does not come into contact with water. See general instructions for use

# 4.6.5. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

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

See general instructions for use

#### 4.7. Use description

Table 7. Use #7 – Mice – Specialized Professional Personnel – Indoors

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: Mus musculus Common name: house mouse Development stage: adults and juvelines
Field(s) of use	indoor use
Application method(s)	Method: in bait boxes  Detailed description: Ready-to-use paste bait in tamper-resistant baits.
Application rate(s) and frequency	Application rate: 20-40 grams of bait per bait holder.

	Dilution (%): -  Number and timing of application: 20-40 grams of bait per bait holder.
Category(ies) of users	trained professional
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of individual bags per container: Up to 25 kg. Grams/kilogram of bait per bag: 10-20 g of bait in bags. Packaging material: PE/Aluminium/Polyester.

### 4.7.1. Use-specific instructions

Remove the remaining product at the end of the treatment. Follow the additional instructions provided by the Manual of Good Practices See also general instructions for use

#### 4.7.2. Use-specific risk mitigation measures

#### 4.7.3. Use-specific risk mitigation measures

Whenever possible, inform bystanders (eg users of the treated area or its surroundings) about the rodent control campaign before treatment. Apply preventative control measures (eg plug holes, remove food and drink where possible) to improve bait intake and reduce the likelihood of reinvasion. To reduce the risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment, in accordance with the provisions of the Good Practices Manual. Do not use the product as a permanent bait for the prevention of rodent infestations or to monitor rodent activity. Do not use the product in pulse priming treatments. See also general instructions for use

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

When bait boxes are placed near water drainage systems make sure the bait does not come into contact with water. See also general instructions for use

# 4.7.5. Where specific to the use, the instructions for safe disposal of the product and its packaging

See also general instructions for use

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

See also general instructions for use

### 4.8. Use description

Table 8. Use #8 - Rats - Specialized Professional Personnel - Indoors.

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: adults and juveniles
Field(s) of use	indoor use
Application method(s)	Method: in bait boxes
	Detailed description: Ready-to-use paste bait in tamper-resistant baits.
Application rate(s) and frequency	Application rate: 100-200 grams of bait per bait holder.  Dilution (%): -  Number and timing of application: 100-200 grams of bait per bait holder.
Category(ies) of users	trained professional
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of individual bags per container: Up to 25 kg. Grams/kilogram of bait per bag: 10-20 g of bait in bags. Packaging material: PE/Aluminium/Polyester.

#### 4.8.1. Use-specific instructions

Remove the remaining product at the end of the treatment. Follow the additional instructions provided by the Manual of Good Practices See also general instructions for use

## 4.8.2. Use-specific risk mitigation measures

#### 4.8.3. Use-specific risk mitigation measures

Whenever possible, inform bystanders (eg users of the treated area or its surroundings) about the rodent control campaign before treatment. Apply preventative control measures (eg plug holes, remove food and drink where possible) to improve bait intake and reduce the likelihood of reinvasion. To reduce the risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment, in accordance with the provisions of the Good Practices Manual. Do not use the product as a permanent bait for the prevention of rodent infestations or to monitor rodent activity. Do not use the product in pulse priming treatments. See also general instructions for use

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

When bait boxes are placed near water drainage systems make sure the bait does not come into contact with water. See also general instructions for use

# 4.8.5. Where specific to the use, the instructions for safe disposal of the product and its packaging

See also general instructions for use

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

See also general instructions for use

## 4.9. Use description

Table 9. Use # 9 – Mice and/or Rats – Specialized professional personnel – Around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat
suge)	Development stage: adults and juveniles
	Scientific name: Mus musculus Common name: house mouse Development stage: adults and juveniles
Field(s) of use	Otro
	around buildings
Application method(s)	Method: in bait boxes
	Detailed description: Ready-to-use paste bait in tamper-resistant baits.
Application rate(s) and frequency	Application rate: Mice: 20-40 grams of bait per bait holder; Rats: 100-200 grams of bait per bait holder
	Dilution (%): -
	Number and timing of application:

	Mice: 20-40 grams of bait per bait holder; Rats: 100-200 grams of bait per bait holder
Category(ies) of users	trained professional
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of individual bags per container: Up to 25 kg. Grams/kilogram of bait per bag: 10-20 g of bait in bags. Packaging material: PE/Aluminium/Polyester.

#### 4.9.1. Use-specific instructions

Protect the baits from atmospheric conditions (eg: rain, snow, etc). Place the bait holder in areas not subject to flooding. Replace baits that have been water damaged or contaminated by dirt. Remove the remaining product at the end of the treatment. Follow the additional instructions provided by the Manual of Good Practices See also general instructions for use

#### 4.9.2. Use-specific risk mitigation measures

### 4.9.3. Use-specific risk mitigation measures

Whenever possible, inform bystanders (eg users of the treated area or its surroundings) about the rodent control campaign before treatment. Apply preventative control measures (eg plug holes, remove food and drink where possible) to improve bait intake and reduce the likelihood of reinvasion. To reduce the risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment, in accordance with the provisions of the Good Practices Manual. Do not use product as a permanent bait to prevent rodent infestation or to detect rodent activity. Do not use the product in pulse priming treatments. Do not apply the product directly in burrows. See also general instructions for use

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

When bait boxes are placed near surface water (eg rivers, lakes, water channels, dams, irrigation canal/ditch) or water drainage systems ensure that the bait does not come into contact with water. See also general instructions for use

# 4.9.5. Where specific to the use, the instructions for safe disposal of the product and its packaging

See also general instructions for use

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

See also general instructions for use

### 5. GENERAL DIRECTIONS FOR USE<sup>1</sup>

#### **5.1.** Instructions for use

General public

Read and follow the product information as well as any other information accompanying the product or provided at the point of sale before using it.Before using rodenticide products, the use of non-chemical methods (eg traps) is recommended.Remove food readily available to rodents (eg loose grain or food waste). Apart from this, do not clean the area to be treated just before the treatment, this will only annoy the rodents and the acceptance of the bait will be more difficult to achieve.Bait boxes should be placed in the vicinity of places where rodent activity has been observed (passage areas, nesting sites, feeders, holes, burrows...)Whenever possible, the bait box should be fixed to the ground or other structures.Do not open the bag containing the bait.Place the bait boxes out of the reach of children, birds, pets, farm animals and other animals for which the product is not intended.It should not be applied in areas where food/feed, beverages, cooking utensils, or food processing surfaces may come into contact with or be contaminated by the product.Do not place bait boxes near water drainage systems where bait can come into contact with water.While using the product do not eat, drink or smoke. Wash hands and exposed skin areas after using product.Remove the remaining bait and the bait holder at the end of the treatment

ProfessionalRead and follow the product information as well as any other information accompanying the product or provided at the point of sale before using it. Conduct a pre-treatment survey of the infested area and an on-site evaluation to identify rodent species, their areas of activity, and determine the cause and extent of the infestation. Remove food readily available to rodents (eg loose grain or food waste). Apart from this, do not clean the area to be treated just before the treatment, this will only annoy the rodents and the acceptance of the bait will be more difficult to achieve. The product should be used as part of a comprehensive pest control plan, including but not limited to hygiene measures and, where possible, physical methods of control.Apply preventative control measures (eg plug holes, remove food and drink as far as possible) to improve bait intake and reduce the likelihood of re-invasion. Bait boxes should be placed in the vicinity of places where rodent activity has been observed (walking areas, nesting sites, feeders, holes, burrows...). Whenever possible, the bait box should be fixed to the ground or other structuresBait boxes must be clearly labeled indicating that they contain a rodenticide product and that they must not be moved or opened (See section 5.3. to see the information that must be included on the label). When the product is used in public areas, the treated areas must be marked during the treatment period and an explanatory sign must inform about the risk of primary and secondary poisoning of anticoagulants as well as first aid measures. The baits must be secured to prevent them from being dragged out of the bait box. Place the bait boxes out of the reach of children, birds, pets, farm animals and other animals for which the product is not intended. It should not be applied in areas where food/ feed, beverages, cooking utensils, or food processing surfaces may come into contact with or be contaminated by the product. Wear chemical resistant protective gloves during the handling phase (glove material to be provided by the authorization holder within the product information). While using the product do not eat, drink or smoke. Wash hands and exposed skin areas after using the product. If the amount of bait ingested is low relative to the apparent size of the infestation, additional bait stations and the possibility of switching to another bait formulation should be considered. If after a treatment period of 35 days it is observed that the baits continue to be consumed and rodent activity does not decrease, the cause must be determined. When other elements have been excluded, the use of a non-anticoagulant rodenticide or a more potent anticoagulant rodenticide may need to be considered for resistant rodents. The use of traps should also be considered as an alternative control measure. Remove the remaining bait and the bait holder at the end of the treatment Specific instructions depending on the type of bait:- Bagged bait: Do not open the bag containing the bait

Specialized professional staffRead and follow the product information as well as any other information accompanying the product or provided at the point of sale before using it. Conduct a pre-treatment survey of the

<sup>&</sup>lt;sup>1</sup>Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

infested area and an on-site evaluation to identify rodent species, their areas of activity, and determine the cause and extent of the infestation. Remove food readily available to rodents (eg loose grain or food waste). Apart from this, do not clean the area to be treated just before the treatment, this will only annoy the rodents and the acceptance of the bait will be more difficult to achieve. The product should be used as part of a comprehensive pest control plan, including but not limited to hygiene measures and, where possible, physical methods of control. The product must be placed in the vicinity of places where rodent activity has been observed (walking areas, nesting sites, feeders, holes, burrows...). Whenever possible, the bait box should be fixed to the ground or other structuresBait boxes must be clearly labeled indicating that they contain rodenticides and that they must not be moved or opened (See section 5.3. to see the information that must be included on the label). When the product is used in public areas, the treated areas must be marked during the treatment period and an explanatory sign must inform about the risk of primary and secondary poisoning of anticoagulants as well as first aid measures. The baits must be secured to prevent them from being dragged out of the bait box. Place bait stations out of reach of children, birds, pets, farm animals, and other non-target animalsIt should not be applied in areas where food/feed, beverages, cooking utensils, or food processing surfaces may come into contact with or be contaminated by the product. Wear chemical resistant protective gloves during the handling phase (glove material to be provided by the authorization holder within the product information). While using the product do not eat, drink or smoke. Wash hands and exposed skin areas after using the product. The frequency of visits to the treated areas should be at the discretion of the applicator, by virtue of the surveys carried out at the beginning of the treatment. This frequency must be consistent with the recommendations provided by the Good Practices Manual. If the amount of bait ingested is low relative to the apparent size of the infestation, additional bait stations and the possibility of switching to another bait formulation should be considered. If after a treatment period of 35 days it is observed that the baits continue to be consumed and rodent activity does not decrease, the cause must be determined. When other elements have been excluded, the use of a non-anticoagulant rodenticide or a more potent anticoagulant rodenticide may need to be considered for resistant rodents. The use of traps should also be considered as an alternative control measure.

#### **5.2.** Risk mitigation measures

General publicApply preventative control measures (eg plug holes, remove food and drink as far as possible) to improve bait intake and reduce the likelihood of re-invasion. Do not use product as a permanent bait to prevent rodent infestation or to detect rodent activity. Product information (eg label and/or brochure) must clearly indicate:- The product will be used in tamper-resistant baits (eg: "use only in tamper-resistant baits").-Users must adequately label the bait boxes with the information included in section 5.3. of the SPC (eg: "label the bait boxes according to the product recommendations"). Use of this product should eliminate rodents within 35 days. Product information (eg label and/or brochure) should recommend that in case of suspected lack of efficacy at the end of treatment (eg rodent activity is still being observed) the user should contact the product supplier or call to a pest control service. Find and remove dead rodents during treatment, at least whenever bait boxes are checked. Dispose of dead rodents as hazardous waste in accordance with municipal ordinances.ProfessionalWhenever possible, before treatment inform bystanders (eg users of the treated area or its surroundings) about the rodent control campaign (according to the applicable code of good practice, if any). To reduce the risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (eg, at least twice a week) (Where relevant, specify if more frequent or daily inspection is required). The products should not be used for more than 35 days without an evaluation of the state of the infestation and the efficacy of the treatment. Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestations or for monitoring rodent activity. Product information (eg label and/or brochure) must clearly indicate:- The product must not be supplied to the general public (eg: "only for professionals")- The product will be used in tamper-resistant baits (eg: "use only in tamper-resistant baits").- Users must adequately label the bait boxes with the information included in section 5.3. of the SPC (eg: "label the bait boxes according to the product recommendations"). Use of this product should eliminate rodents within 35 days. Product information (eg label and/or brochure) should recommend that in case of suspected lack of efficacy at the end of treatment (eg rodent activity is still being observed) the user should contact the product supplier or call to a pest control service. Do not wash the bait box with water between applications. Dispose of dead rodents as hazardous waste in accordance with municipal ordinances. specialized professionalWhenever possible, inform by standers about the rodent control campaign before treatment

(according to the applicable code of good practice, if any). The product information (eg label and/or brochure) will clearly indicate that the product will only be supplied to specialized professional users holding a training certificate. (eg: "only for specialized professional personnel"). Do not use in areas where resistance to the active substance is suspected. Products should not be used for more than 35 days without evaluation of infestation status and treatment efficacy (unless permanent baiting is authorised). Do not alternate the use of different anticoagulant active substances with comparable or lower potencies for the purpose of managing resistance. If they alternate, consider the use of non-anticoagulant rodenticides, if available, or a more potent anticoagulant rodenticide. Do not wash the bait holder or other utensils used in the covered or protected bait points with water between applications. Eliminate dead rodents through an authorized hazardous waste manager, in accordance with current regulations. Incineration is recommended as a treatment method.

# 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 swallowed, symptoms may become apparent within 72 hours. Clinical manifestations may include bleeding from the nose and gums. In severe cases, there may be bruising and blood in the stool or urine. Antidote: Vitamin K1 administered only by medical/veterinary personnel. In case of: Dermal exposure, wash skin with water and then with soap and water. Eye exposure, always check the presence of contact lenses and remove them, rinse the eyes with liquid to rinse the eyes or water, keep the eyes open for at least 10 minutes. Oral exposure, rinse mouth carefully with water. Do not give anything by mouth to an unconscious person. Do not induce vomiting. If ingested, seek medical advice, keep the label or container at hand and consult the TOXICOLOGICAL INFORMATION SERVICE (Phone 91 562 04 20). Contact a veterinarian in case of ingestion by a pet. Bait boxes must be labeled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorization number"; "active substance(s)"; "in case of accident, call the TOXICOLOGICAL INFORMATION SERVICE". Dangerous for wildlife.

#### 5.4. Instructions for safe disposal of the product and its packaging

For the general public, the use of gloves is recommended. General public and professional - At the end of the treatment, dispose of the unconsumed bait and the container as hazardous waste in accordance with the provisions of the municipal ordinances. The following shall be indicated on the label of the bait holders: - Eliminate the bait holders, at the end of their useful life, as hazardous waste in accordance with the provisions of the municipal ordinances. - specialized professional - At the end of the treatment, dispose of the unconsumed bait and the container through an authorized hazardous waste manager, in accordance with current regulations. - Incineration is recommended as a treatment method. The following shall be indicated on the label of the bait holders: - Dispose of the bait holders, at the end of their useful life, through an authorized hazardous waste manager, in accordance with current regulations.

# 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 light. Keep out of reach of children, birds, pets and farm animals. The product is stable for 2 years

#### 6. OTHER INFORMATION

Due to the delayed mode of action, anticoagulant rodenticides may take 4-10 days to become effective after bait consumption. Rodents are transmitters of diseases. Do not touch dead rodents with bare hands, use gloves or utensils such as tweezers for disposal. This product contains a bittering agent and a colorant. Definitions of interest in the context of the use of anticoagulant rodenticides in Spain: Non-professional personnel (general public) are non-professional users who apply the product in the context of their private life. Professional personnel are considered to be those who carry out their professional activity in the environment of animals or in activities closely related to their exploitation. Specialized professional personnel is considered to be the applicator of biocidal products, who has received specific training in rodenticide control, in accordance with current legislation. Data required after authorization: The holder of the authorization must inform the Competent Authorities before the next renewal of the product about any incident that he suspects has occurred to wildlife, domestic animals or livestock that may have been caused by the use of the product. The data may be collected from veterinary clinics, animal protection NGOs or citizen complaints.