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*ANNEX*

**SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT**

BRODITEC P-17

**Product type(s)**

PT14: Rodenticides

**Authorisation number:** FR-2023-0017

**R4BP asset number:** FR-0023967-0000

## 1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	BRODITEC P-17 Broditop Strike P Broditop Matrix P Broditop LC P Zed Strike P Zed Matrix P Zed LC P Rodibrod Strike P Rodibrod Matrix P Rodibrod LC P Protemax Strike P Protemax Matrix P Protemax LC P Deviltop Strike P Deviltop Matrix P Deviltop LC P ZAPI-TOP Strike P ZAPI-TOP Matrix P ZAPI-TOP LC P ZAPI-RAT Strike P ZAPI-RAT Matrix P ZAPI-RAT LC P MUSKIL PATE APPÂTS DEVILTOP PATE APPÂTS BRODITOP PATE APPÂTS RODIBROD PATE APPÂTS ACTO RATS-SOURIS PÂTE APPÂT BR
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### 1.2. Authorisation holder

Name and address of the authorisation holder	Name	ZAPI S.p.A.
	Address	via Terza Strada 12 35026 Conselve Italy
Authorisation number		FR-2023-0017
<i>R4BP asset number</i>		FR-0023967-0000
Date of the authorisation		06/03/2023
Expiry date of the authorisation		16/02/2028

### 1.3. Manufacturer(s) of the product

Name of manufacturer	Zapi S.p.A.
Address of manufacturer	Via Terza Strada 12 35026 Conselve Italy
Location of manufacturing sites	Zapi S.p.A. site 1 Via Terza Strada 12 35026 Conselve Italy

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

Active substance	Brodifacoum
Name of manufacturer	P.M. Tezza S.r.l. (Art. 95 list: ACTIVA S.r.l.)

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Address of manufacturer	Via del Lavoro 326 37050 Angiari (VR) Italy
Location of manufacturing sites	P.M. Tezza S.r.l. site 1 Via Tre Ponti 22 37050 S.Maria di Zevio (VR) Italy

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## 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-naphthyl]-4-hydroxycoumarin	active substance	56073-10-0	259-980-5	0,0017

### 2.2. Type(s) of formulation

RB - Bait (ready to use paste)

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### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	
Precautionary statements	

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. House 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)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles and adults
Field(s) of use	indoor use  indoor
Application method(s)	Method: bait application  Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: Bait products: 30-50g of bait per baiting point separated by 2-5m.  Number and timing of application: Bait products: 30-50g of bait per baiting point separated by 2-5m.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Maximum quantity of bait per unit sold: 150g (product for mice and rats) Single dose filter paper sachets :  <ul style="list-style-type: none"><li>• for pre-filled bait station: 10g or 15g</li><li>• for the other packs: 15g</li></ul> Single dose filter paper sachets (15g) packed in: - 30g to 150g Blister (PVC or PVC + carton) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (LDPE) - 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Non-coated electrolytic tin plate metal can with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Box (carton) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)

	<p>- 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</p> <p>- 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s) enveloped in a protective polyolefin film (PP or PET or PVC or HDPE)</p> <p>- 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</p> <p>* the bait station could be enveloped in a protective polyolefin film.</p>
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**4.1.1. Use-specific instructions**

- 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.

**4.1.2. Use-specific risk mitigation measures**

**4.1.3. Use-specific risk mitigation measures**

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**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**

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

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

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**4.2. Use description**

**Table 2. Rats – general public – indoor**

Product type	PT14: Rodenticides
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Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	<p>Scientific name: <i>Rattus norvegicus</i>  Common name: brown rat  Development stage: juveniles and adults</p> <p>Scientific name: <i>Rattus rattus</i>  Common name: roof rat  Development stage: juveniles and adults</p>
Field(s) of use	<p>indoor use</p> <p>indoor</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations</p>
Application rate(s) and frequency	<p>Application rate: Bait products: 60-80g of bait per baiting point spaced 5-10m apart.</p> <p>Number and timing of application:  Bait products:  60-80g of bait per baiting point spaced 5-10m apart.</p>
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<p>Maximum quantity of bait per unit sold: 150g (product for mice and rats).  Single dose filter paper sachets :</p> <ul style="list-style-type: none"> <li>• for pre-filled bait station: 10g or 15g</li> <li>• for the other packs: 15g</li> </ul> <p>Single dose filter paper sachets (15g) packed in:</p> <ul style="list-style-type: none"> <li>- 30g to 150g Blister (PVC or PVC + carton) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> <li>- 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (LDPE)</li> <li>- 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> <li>- 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> <li>- 30g to 150g Non-coated electrolytic tin plate metal can with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> <li>- 30g to 150g Box (carton) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> <li>- 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> </ul>



	<p>- 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s) enveloped in a protective polyolefin film (PP or PET or PVC or HDPE)</p> <p>- 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</p> <p>* the bait station could be enveloped in a protective polyolefin film.</p>
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**4.2.1. Use-specific instructions**

- 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.

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

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

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**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**

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

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

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**4.3. Use description**

**Table 3. Rats – general public – outdoor 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)	<p>Scientific name: <i>Rattus norvegicus</i>  Common name: brown rat  Development stage: juveniles and adults</p> <p>Scientific name: <i>Rattus rattus</i>  Common name: roof rat  Development stage: juveniles and adults</p>
Field(s) of use	<p>outdoor use</p> <p>outdoor around buildings</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations</p>
Application rate(s) and frequency	<p>Application rate: Bait products: 60-80g of bait per baiting point spaced 5-10m apart.</p> <p>Number and timing of application:  Bait products:  60-80g of bait per baiting point spaced 5-10m apart.</p>
Category(ies) of users	<p>general public (non-professional)</p>
Pack sizes and packaging material	<p>Maximum quantity of bait per unit sold: 150g (product for mice and rats).  Single dose filter paper sachets :</p> <ul style="list-style-type: none"> <li>• for pre-filled bait station: 10g or 15g</li> <li>• for the other packs: 15g</li> </ul> <p>Single dose filter paper sachets (15g) packed in:</p> <ul style="list-style-type: none"> <li>- 30g to 150g Blister (PVC or PVC + carton) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> <li>- 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (LDPE)</li> <li>- 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> <li>- 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> <li>- 30g to 150g Non-coated electrolytic tin plate metal can with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> <li>- 30g to 150g Box (carton) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> <li>- 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)</li> <li>- 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s) enveloped in a protective polyolefin film (PP or PET or PVC or HDPE)</li> </ul>

- 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) with inner pre-filled tamper resistant bait station(s)\* (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)

\* the bait station could be enveloped in a protective polyolefin film.

#### 4.3.1. Use-specific instructions

- 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.

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

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

- Do not use the product close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches).

#### 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

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

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

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#### 4.4. Use description

**Table 4. Not relevant in France – House mice – professionals – 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: <i>Mus musculus</i> Common name: house mouse

	Development stage: juveniles and adults
Field(s) of use	indoor use indoor
Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: Bait products: 30-50 g of bait per baiting point spaced 2-5m apart.  Number and timing of application: Bait products: 30-50 g of bait per baiting point spaced 2-5m apart.
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 3 kg. <i>(In France only : minimum pack size of 5 kg)</i>  Single dose filter paper sachets (10 or 15g) packed in: - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE) - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner liner (LDPE) - 3 kg to 25 kg Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film - 3 kg to 25 kg Sack (LDPE or LDPE/paper)

#### 4.4.1. Use-specific instructions

- The bait stations should be visited at least every 2 to 3 days for mice 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.
- *[When available]* Follow any additional instructions provided by the relevant code of best practice.

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

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

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

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

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

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**4.5. Use description**

**Table 5. Not relevant in France – Rats – professionals – 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: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults  Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: juveniles and adults
Field(s) of use	indoor use  indoor
Application method(s)	Method: bait application  Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: Bait products: 60-80 g of bait per baiting point spaced 5-10m apart.  Number and timing of application: Bait products: 60-80 g of bait per baiting point spaced 5-10m apart.
Category(ies) of users	professional
Pack sizes and packaging material	Minimum pack size of 3 kg. <i>(In France only : minimum pack size of 5 kg)</i>  Single dose filter paper sachets (10 or 15g) packed in: - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE)

	<ul style="list-style-type: none"> <li>- 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner liner (LDPE)</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film</li> <li>- 3 kg to 25 kg Sack (LDPE or LDPE/paper)</li> </ul>
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**4.5.1. Use-specific instructions**

- 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.
- [*When available*] Follow any additional instructions provided by the relevant code of best practice.

**4.5.2. Use-specific risk mitigation measures**

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

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

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

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

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**4.6. Use description**

**Table 6. Not relevant in France – House mice and rats – professionals outdoor around buildings**

Product type	PT14: Rodenticides
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Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i>  Common name: house mouse  Development stage: - juveniles and adults</p> <p>Scientific name: <i>Rattus norvegicus</i>  Common name: brown rat  Development stage: - juveniles and adults</p> <p>Scientific name: <i>Rattus rattus</i>  Common name: roof rat  Development stage: - juveniles and adults</p>
Field(s) of use	<p>outdoor use</p> <p>outdoor around buildings</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations</p>
Application rate(s) and frequency	<p>Application rate: Bait products: Mice: 30-50 g of bait per baiting point spaced 2-5m apart. Rats: 60-80 g of bait per baiting point spaced 5-10m apart.</p> <p>Number and timing of application:  Bait products:</p> <p>Mice:  30-50 g of bait per baiting point spaced 2-5m apart.</p> <p>Rats:  60-80 g of bait per baiting point spaced 5-10m apart.</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.  <i>(In France only : minimum pack size of 5 kg)</i></p> <p>Single dose filter paper sachets (10 or 15g) packed in:</p> <ul style="list-style-type: none"> <li>- 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE)</li> <li>- 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner liner (LDPE)</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film</li> <li>- 3 kg to 25 kg Sack (LDPE or LDPE/paper)</li> </ul>

#### 4.6.1. Use-specific instructions

- 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 [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.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

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

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

- Do not apply this product directly in the burrows.
- Do not use the product close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches).

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

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

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

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#### 4.7. Use description

**Table 7. House mice and rats – trained professionals – 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: <i>Mus musculus</i> Common name: house mouse Development stage: - juveniles and adults  Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: - juveniles and adults  Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: - juveniles and adults
Field(s) of use	indoor use  indoor
Application method(s)	Method: bait application



	Detailed description: Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points
Application rate(s) and frequency	<p>Application rate: Bait products: Mice: 30-50 g of bait per baiting point spaced 2-5m apart. Rats: 60-80 g of bait per baiting point spaced 5-10m apart.</p> <p>Number and timing of application: Bait products:</p> <p>Mice: 30-50 g of bait per baiting point spaced 2-5m apart.</p> <p>Rats: 60-80 g of bait per baiting point spaced 5-10m apart.</p>
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg. <i>(In France only : minimum pack size of 5 kg)</i></p> <p>Single dose filter paper sachets (10 or 15g) packed in:</p> <ul style="list-style-type: none"> <li>- 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE)</li> <li>- 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner liner (LDPE)</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner pre-filled tamper resistant bait station(s)* enveloped in a protective polyolefin film (PP or PET or PVC or HDPE)</li> <li>- 3 kg to 25 kg Sack (LDPE or LDPE/paper)</li> </ul> <p>* the bait station could be enveloped in a protective polyolefin film.</p>

#### 4.7.1. Use-specific instructions

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

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

#### 4.7.3. 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.

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

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

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

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**4.8. Use description**

**Table 8. House mice and rats – trained professionals – outdoor 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)	<p>Scientific name: <i>Mus musculus</i>  Common name: house mouse  Development stage: - juveniles and adults</p> <p>Scientific name: <i>Rattus norvegicus</i>  Common name: brown rat  Development stage: - juveniles and adults</p> <p>Scientific name: <i>Rattus rattus</i>  Common name: roof rat  Development stage: - juveniles and adults</p>
Field(s) of use	<p>outdoor use</p> <p>outdoor around buildings</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points - Direct application of ready-to-use bait into the burrow</p>
Application rate(s) and frequency	<p>Application rate: Bait products: Mice: 30-50 g of bait per baiting point spaced 2-5m apart. Rats: 60-80 g of bait per baiting point spaced 5-10m apart.</p> <p>Number and timing of application:  Bait products:  Mice:</p>

	30-50 g of bait per baiting point spaced 2-5m apart.  Rats: 60-80 g of bait per baiting point spaced 5-10m apart.
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg. <i>(in France only</i> : Minimum pack size of 5 kg)</p> <p>Single dose filter paper sachets (10 or 15g) packed in:</p> <ul style="list-style-type: none"> <li>- 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE)</li> <li>- 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner liner (LDPE)</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg</li> <li>- 3 kg to 25 kg Carton box or box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film (from 3 kg to 25 kg);</li> <li>- 3 kg to 25 kg Sack (LDPE or LDPE/paper)</li> </ul> <p>* the bait station could be enveloped in a protective polyolefin film.</p>

#### 4.8.1. Use-specific instructions

- 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 for direct application into the burrow).
- *[When available]* Follow any additional instructions provided by the relevant code of best practice.
- *[For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species].*

*For directly application into the burrow:*

- 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.

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

#### 4.8.3. 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 use the product close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches).

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

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

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

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

### 5.1. Instructions for use

#### FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS

- 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.
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (*see section 5.3 for the information to be shown on the label*).
- *[If national policy or legislation requires it]* 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.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Do not open the sachets containing the bait.

#### FOR TRAINED PROFESSIONAL ONLY

- 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.
- 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.).

#### FOR PROFESSIONALS ONLY

- 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.
- Remove the remaining bait or the bait stations at the end of the treatment period.
- The bait station 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.).

#### FOR NON PROFESSIONAL USERS

- 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.

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

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- 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.

## **5.2. Risk mitigation measures**

### **FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS**

- 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*].

### **FOR TRAINED PROFESSIONAL ONLY**

- 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*].
- 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*].

### **FOR PROFESSIONAL ONLY:**

- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). [*Where relevant, specify if more frequent or daily inspection is required*].
- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- The product information (i.e. label and/or leaflet) shall clearly show that:
  - the product shall not be supplied to the general public (e.g. "for professionals only").
  - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
  - users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- 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*].

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- 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 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*]

#### **FOR NON PROFESSIONAL USERS**

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

### **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.
- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- IF SWALLOWED: Rinse mouth.  
If symptoms: Call 112/ambulance for medical assistance.  
If no symptoms: Call a POISON CENTRE or a doctor.  
Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.  
Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information].
- If medical advice is needed, have product container or label at hand.
- 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.

### **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*].
- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

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### **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: 3 years.
- Store the product at temperatures below 35°C.
- Protect from light.
- Do not store near food, drink and feed.



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## **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.