

**EN**

*ANNEX*

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

BRODITEC P-17F

**Product type(s)**

PT14: Rodenticides

**Authorisation number:** ES/MR(NA)-2023-14-00892

**R4BP asset number:** ES-0030106-0000

## 1. ADMINISTRATIVE INFORMATION

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

|               |  |
|---------------|--|
| Trade name(s) | BRODITEC P-17F<br>Broditop Fit<br>Broditop Fit Pasta Fluo-NP<br>Broditop Innova Pasta<br>Broditop Innova Pasta Fluo-NP<br>Broditop LC PF<br>Broditop Matrix PF<br>Broditop Performance Pasta<br>Broditop Performance Pasta Fluo-NP<br>Broditop PR<br>Broditop Strike PF<br>Zed Strike PF<br>Zed Matrix PF<br>Zed LC PF<br>Rodibrod Strike PF<br>Rodibrod Matrix PF<br>Rodibrod LC PF<br>Protemax Strike PF<br>Protemax Matrix PF<br>Protemax LC PF<br>RASQUIM PASTA NT BF17<br>Deviltop Strike PF<br>IFA SABE raticida cebo fresco<br>Deviltop Matrix PF<br>Deviltop LC PF<br>ZAPI-TOP Strike PF<br>ZAPI-TOP Matrix PF<br>ZAPI-TOP LC PF<br>ZAPI-RAT Strike PF<br>ZAPI-RAT Matrix PF<br>ZAPI-RAT LC PF |
|---------------|--|

### 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                         |         | ES/MR(NA)-2023-14-00892                  |
| <i>R4BP asset number</i>                     |         | ES-0030106-0000                          |
| Date of the authorisation                    |         | 20/10/2023                               |
| 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 Zapi S.p.A. Via Terza Strada 12 35026 Italy |

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

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|                                 |  |
|---------------------------------|--|
| Active substance                | Brodifacoum  |
| Name of manufacturer            | P.M. Tezza S.r.l.  |
| 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<br>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 | 0,00171 % (w/w) |

### 2.2. Type(s) of formulation

RB Bait (ready for use)

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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><br>Common name: house mouse<br>Development stage: juveniles and adults  |
| Field(s) of use  | indoor use<br><br>Indoor   |
| Application method(s)                                      | Method: in bait boxes<br><br>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations  |
| Application rate(s) and frequency                          | Application rate: Bait application<br><br>Dilution (%): /<br><br>Number and timing of application:<br>- High infestation: 30-50 g of bait per baiting point spaced 2m apart.<br><br>- Low infestation: 30-50 g of bait per baiting point spaced 5m apart.  |
| Category(ies) of users                                     | general public (non-professional)  |
| Pack sizes and packaging material                          | Maximum quantity of bait per unit sold:<br><br>- 50g (product for mice): single dose filter paper sachets (10g or 15g)<br><br>- 150g (product for mice and rats): single dose filter paper sachets (for pre-filled bait station: 10g or 15g, for the other packs: 15g)<br><br>Single dose filter paper sachets (10g or 15g) packed in:<br><br>- Blister (PVC or PVC + carton) with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g); |

- Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (PE or LDPE) (from 30g to 150g);
  - Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);
  - Bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);
  - Non-coated electrolytic tin plate metal can with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);
  - Box (carton) with inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);
  - Box (carton) with inner pre-filled tamper resistant bait station(s)\* (PP or PET or PVC or HDPE) with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);
  - Bag (PE or PE/OPA or PE/PET or PE/OPA/PET) with inner pre-filled tamper resistant bait station(s)\* (PP or PET or PVC or HDPE) with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (30g-150g);
- \* the bait station could be enveloped in a protective polyolefin film.

#### **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**

See section Directions for use - risk mitigation measures

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#### 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 Directions for use - particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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

See section Directions for use - instructions for safe disposal of the product and its packaging

#### 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 Directions for use - conditions of storage and shelf-life of the product under normal conditions of storage

### 4.2. Use description

**Table 2. Rats – 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>Rattus norvegicus</i><br>Common name: brown rat<br>Development stage: juveniles and adults<br><br>Scientific name: <i>Rattus rattus</i><br>Common name: roof rat<br>Development stage: juveniles and adults |
| Field(s) of use  | indoor use<br><br>Indoor  |
| Application method(s)                                      | Method: in bait boxes<br><br>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations   |
| Application rate(s) and frequency                          | Application rate: Bait application<br><br>Dilution (%): /<br><br>Number and timing of application:<br>Rats:   |



|                                   |   |
|-----------------------------------|---|
|                                   | <ul style="list-style-type: none"> <li>- High infestation: 60-80 g of bait per baiting point spaced 5m apart.</li> <li>- Low infestation: 60-80 g of bait per baiting point spaced 10m apart.</li> </ul>  |
| Category(ies) of users            | general public (non-professional)   |
| Pack sizes and packaging material | <p>Maximum quantity of bait per unit sold:</p> <ul style="list-style-type: none"> <li>- 50g (product for mice): single dose filter paper sachets (10g or 15g)</li> <li>- 150g (product for mice and rats): single dose filter paper sachets (for pre-filled bait station: 10g or 15g, for the other packs: 15g)</li> </ul> <p>Single dose filter paper sachets (10g or 15g) packed in:</p> <ul style="list-style-type: none"> <li>- Blister (PVC or PVC + carton) with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);</li> <li>- Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (PE or LDPE) (from 30g to 150g);</li> <li>- Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);</li> <li>- Bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);</li> <li>- Non-coated electrolytic tin plate metal can with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);</li> <li>- Box (carton) with inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);</li> <li>- Box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);</li> </ul> |

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

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

#### **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**

See section Directions for use - risk mitigation measures

#### **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 Directions for use - particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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

See section Directions for use - instructions for safe disposal of the product and its packaging

#### **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 'Directions for use'

### **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><br/> Common name: brown rat<br/> Development stage: juveniles and adults</p> <p>Scientific name: <i>Rattus rattus</i><br/> Common name: roof rat<br/> Development stage: juveniles and adults</p>   |
| Field(s) of use  | <p>outdoor use</p> <p>Outdoor around buildings</p>   |
| Application method(s)                                      | <p>Method: in bait boxes</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 application</p> <p>Dilution (%): /</p> <p>Number and timing of application:<br/> - High infestation: 60-80 g of bait per baiting point spaced 5m apart.<br/> - Low infestation: 60-80 g of bait per baiting point spaced 10m apart.</p>  |
| Category(ies) of users                                     | general public (non-professional)  |
| Pack sizes and packaging material                          | <p>Maximum quantity of bait per unit sold:</p> <p>- 50g (product for mice): single dose filter paper sachets (10g or 15g)</p> <p>- 150g (product for mice and rats): single dose filter paper sachets (for pre-filled bait station: 10g or 15g, for the other packs: 15g)</p> <p>Single dose filter paper sachets (10g or 15g) packed in:</p> <p>- Blister (PVC or PVC + carton) with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);</p> <p>- Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (PE or LDPE) (from 30g to 150g);</p> |

- Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);

- Bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);

- Non-coated electrolytic tin plate metal can with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);

- Box (carton) with inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);

- Box (carton) with inner pre-filled tamper resistant bait station(s)\* (PP or PET or PVC or HDPE) with or without inner bag (PE or PE/OPA or PE/PET or PE/OPA/PET) (from 30g to 150g);

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

\* 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**

See section Directions for use - risk mitigation measures

#### **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**

See section Directions for use - particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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

See section Directions for use - instructions for safe disposal of the product and its packaging

#### 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 Directions for use - conditions of storage and shelf-life of the product under normal conditions of storage

### 4.4. Use description

**Table 4. House mice and 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>Mus musculus</i><br>Common name: house mouse<br>Development stage: juveniles and adults<br><br>Scientific name: <i>Rattus norvegicus</i><br>Common name: brown rat<br>Development stage: juveniles and adults<br><br>Scientific name: <i>Rattus rattus</i><br>Common name: roof rat<br>Development stage: juveniles and adults |
| Field(s) of use  | indoor use<br><br>Indoor   |
| Application method(s)                                      | Method: in bait boxes<br><br>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations  |
| Application rate(s) and frequency                          | Application rate: Bait application<br><br>Dilution (%): /<br><br>Number and timing of application:<br>Mice:<br>- High infestation: 30-50 g of bait per baiting point spaced 2m apart.<br>- Low infestation: 30-50 g of bait per baiting point spaced 5m apart.   |

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

#### 4.4.1. 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 for mice, only 5 to 7 days after the beginning of the treatment and at least weekly afterwards for rats, 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

See section Directions for use - risk mitigation measures

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**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.

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

See section Directions for use - instructions for safe disposal of the product and its packaging

**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 Directions for use - instructions for safe disposal of the product and its packaging

**4.5. Use description**

**Table 5. House mice and rats – 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)           | Scientific name: <i>Mus musculus</i><br>Common name: house mouse<br>Development stage: juveniles and adults<br><br>Scientific name: <i>Rattus norvegicus</i><br>Common name: brown rat<br>Development stage: juveniles and adults<br><br>Scientific name: <i>Rattus rattus</i><br>Common name: roof rat<br>Development stage: juveniles and adults |
| Field(s) of use  | outdoor use<br><br>Outdoor around buildings  |
| Application method(s)                                      | Method: in bait boxes  |

|                                   |   |
|-----------------------------------|---|
|                                   | Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations  |
| Application rate(s) and frequency | <p>Application rate: Bait application</p> <p>Dilution (%): /</p> <p>Number and timing of application:</p> <p>Mice:</p> <ul style="list-style-type: none"> <li>- High infestation: 30-50 g of bait per baiting point spaced 2m apart.</li> <li>- Low infestation: 30-50 g of bait per baiting point spaced 5m apart.</li> </ul> <p>Rats:</p> <ul style="list-style-type: none"> <li>- High infestation: 60-80 g of bait per baiting point spaced 5m apart.</li> <li>- Low infestation: 60-80 g of bait per baiting point spaced 10m apart.</li> </ul>  |
| Category(ies) of users            | professional  |
| Pack sizes and packaging material | <p>Minimum quantity of bait per unit sold: 30 g (for mice) or 60g (for mice and rats)</p> <p>Single dose filter paper sachets (10 or 15g) packed in:</p> <ul style="list-style-type: none"> <li>- Bucket (PP or PET or PVC or HDPE) with or without inner liner (PE or LDPE) (from 30g to 25 kg)</li> <li>- Bucket (PP or PET or PVC or HDPE) with inner bag(s) (PE or PE/OPA or PE/PET or PE/OPA/PET) each up to 1 kg (from 30g to 25 kg)</li> <li>- Carton box or box (carton) with inner liner (PE or LDPE) (from 30g to 25 kg)</li> <li>- Carton box or box (carton) with inner bag(s) (PE or PE/OPA or PE/PET or PE/OPA/PET) each up to 1 kg (from 30g to 25 kg)</li> <li>- Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) * (PP or PET or PVC or HDPE) (from 30g to 25 kg)</li> <li>- Sack (PE or PE/paper) (from 30g to 25 kg)</li> </ul> <p>* the bait station could be enveloped in a protective polyolefin film.</p> |

#### 4.5.1. 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 at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards for mice, only 5 to 7 days after the beginning of the treatment and at least weekly afterwards for rats, 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.



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

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

- Do not apply this product directly in the burrows.

#### **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**

- 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.

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

See section Directions for use - instructions for safe disposal of the product and its packaging

#### **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 Directions for use - conditions of storage and shelf-life of the product under normal conditions of storage

### **4.6. Use description**

**Table 6. 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><br>Common name: house mouse<br>Development stage: juveniles and adults<br><br>Scientific name: <i>Rattus norvegicus</i><br>Common name: brown rat<br>Development stage: juveniles and adults<br><br>Scientific name: <i>Rattus rattus</i><br>Common name: roof rat<br>Development stage: juveniles and adults |
| Field(s) of use  | indoor use   |

|                                   |   |
|-----------------------------------|---|
|                                   | Indoor  |
| Application method(s)             | Method: bait application<br><br>Detailed description: - Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points   |
| Application rate(s) and frequency | Application rate: Bait products:<br><br>Dilution (%): /<br><br>Number and timing of application:<br><b>Mice:</b><br><br>- High infestation: 30-50 g of bait per baiting point spaced 2m apart.<br>- Low infestation: 30-50 g of bait per baiting point spaced 5m apart.<br><br><b>Rats:</b><br>- High infestation: 60-80 g of bait per baiting point spaced 5m apart.<br>- Low infestation: 60-80 g of bait per baiting point spaced 10m apart.   |
| Category(ies) of users            | trained professional  |
| Pack sizes and packaging material | Minimum quantity of bait per unit sold: 30 g (for mice) or 60g (for mice and rats)<br><br>Single dose filter paper sachets (10 or 15g) packed in:<br>- Bucket (PP or PET or PVC or HDPE) with or without inner liner (PE or LDPE) (from 30g to 25 kg)<br>- Bucket (PP or PET or PVC or HDPE) with inner bag(s) (PE or PE/OPA or PE/PET or PE/OPA/PET) each up to 1 kg (from 30g to 25 kg)<br>- Carton box or box (carton) with inner liner (PE or LDPE) (from 30g to 25 kg)<br>- Carton box or box (carton) with inner bag(s) (PE or PE/OPA or PE/PET or PE/OPA/PET) each up to 1 kg (from 30g to 25 kg)<br>- Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) * (PP or PET or PVC or HDPE) (from 30g to 25 kg)<br>- Sack (PE or PE/paper) (from 30g to 25 kg)<br><br>* the bait station could be enveloped in a protective polyolefin film. |

#### 4.6.1. 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.

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#### 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 [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.

#### 4.6.3. 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.

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

See section Directions for use - instructions for safe disposal of the product and its packaging

#### 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 Directions for use - conditions of storage and shelf-life of the product under normal conditions of storage

#### 4.7. Use description

**Table 7. 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)           | Scientific name: <i>Mus musculus</i><br>Common name: house mouse<br>Development stage: juveniles and adults<br><br>Scientific name: <i>Rattus norvegicus</i><br>Common name: brown rat |

|                                   |   |
|-----------------------------------|---|
|                                   | <p>Development stage: juveniles and adults</p> <p>Scientific name: Rattus rattus<br/>Common name: roof rat<br/>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; - 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 application</p> <p>Dilution (%): /</p> <p>Number and timing of application:</p> <p>Mice:</p> <ul style="list-style-type: none"> <li>- High infestation: 30-50 g of bait per baiting point spaced 2m apart.</li> <li>- Low infestation: 30-50 g of bait per baiting point spaced 5m apart.</li> </ul> <p>Rats:</p> <ul style="list-style-type: none"> <li>- High infestation: 60-80 g of bait per baiting point spaced 5m apart.</li> <li>- Low infestation: 60-80 g of bait per baiting point spaced 10m apart.</li> </ul>  |
| Category(ies) of users            | trained professional  |
| Pack sizes and packaging material | <p>Minimum quantity of bait per unit sold: 30 g (for mice) or 60g (for mice and rats)</p> <p>Single dose filter paper sachets (10 or 15g) packed in:</p> <ul style="list-style-type: none"> <li>- Bucket (PP or PET or PVC or HDPE) with or without inner liner (PE or LDPE) (from 30g to 25 kg)</li> <li>- Bucket (PP or PET or PVC or HDPE) with inner bag(s) (PE or PE/OPA or PE/PET or PE/OPA/PET) each up to 1 kg (from 30g to 25 kg)</li> <li>- Carton box or box (carton) with inner liner (PE or LDPE) (from 30g to 25 kg)</li> <li>- Carton box or box (carton) with inner bag(s) (PE or PE/OPA or PE/PET or PE/OPA/PET) each up to 1 kg (from 30g to 25 kg)</li> <li>- Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) * (PP or PET or PVC or HDPE) (from 30g to 25 kg)</li> <li>- Sack (PE or PE/paper) (from 30g to 25 kg)</li> </ul> |

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|  | * the bait station could be enveloped in a protective polyolefin film. |
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#### **4.7.1. 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).
- Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species
- [When available] Follow any additional instructions provided by the relevant code of best practice.

##### For direct 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.

#### **4.7.2. 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 [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.

#### **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.

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

See section Directions for use - instructions for safe disposal of the product and its packaging

#### **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 Directions for use - 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 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.

### FOR 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 (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 5.3 for the information to be shown on the label).
- [If national policy or legislation require 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.

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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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- 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.
- Do not open the sachets containing the bait.

### **FOR 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.
  - [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.
  - The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.
  - If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
  - If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Do not open the sachets containing the bait.



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## **5.2. Risk mitigation measures**

### **FOR 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 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.

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

### **FOR TRAINED PROFESSIONALS**

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign [*in accordance with the applicable code of good practice, if any*].
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

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- 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.

### **5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- In case of:
  - Dermal exposure, wash skin with water and then with water and soap.
  - Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
  - Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information]
  - Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of accident, call a poison center"
- 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.
  
- [For general public]: use of gloves is recommended.

### **5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- Store in places prevented from the access of children, birds, pets and farm animals.
- Shelf life: 2 years.

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## **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.