

**EN**

***ANNEX***

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

DIFENABLEU BLOCK

**Product type(s)**

PT14: Rodenticides

**Authorisation number:** IT/2012/00037/AUT

**R4BP asset number:** IT-0002296-0000

## 1. ADMINISTRATIVE INFORMATION

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

|               |                  |
|---------------|------------------|
| Trade name(s) | DIFENABLEU BLOCK |
|---------------|------------------|

### 1.2. Authorisation holder

|  |                   |                                |
|--|-------------------|--------------------------------|
| Name and address of the authorisation holder | Name              | Bleu Line S.r.l.               |
|  | Address           | Virgilio, 28 47122 Forlì Italy |
| Authorisation number                         | IT/2012/00037/AUT |                                |
| <i>R4BP asset number</i>                     | IT-0002296-0000   |                                |
| Date of the authorisation                    | 11/06/2012        |                                |
| Expiry date of the authorisation             | 31/12/2026        |                                |

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

|                                 |  |
|---------------------------------|--|
| Name of manufacturer            | BLEU LINE S.r.l.   |
| Address of manufacturer         | Via Virgilio, 28 - Z.I. Villanova 47122 Forlì (FC) Italy   |
| Location of manufacturing sites | FERBI S.r.l. - Viale 1° Maggio - C/da Ripoli 64023<br>Mosciano S.Angelo (TE) Italy<br><br>INDUSTRIALCHIMICA S.r.l. - Via Sorgaglia, 25<br>35020 Arre (PD) Italy<br><br>VEBI ISTITUTO BIOCHIMICO S.r.l. - Via Desman,<br>43 35010 S.Eufemia di Borgoricco (PD) Italy<br><br>G.M.B. Internacional S.A. - Avenida Mas del Oli, 144<br>46940 Manises (Valencia) Spain<br><br>BIOSOL ITALIA S.r.l.s. - Via Nettunense Km 23,400<br>04011 Aprilia (LT) Italy<br><br>SELECTA S.r.l. (packaging operations only) - Via<br>Tacito, 9 20094 Corsico (MI) Italy |

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

|                                 |  |
|---------------------------------|--|
| Active substance                | Difenacoum   |
| Name of manufacturer            | Activa S.r.l.  |
| Address of manufacturer         | Via Feltre, 32 20132 Milano Italy  |
| Location of manufacturing sites | Dr Tezza S.r.l. - Via Tre Ponti, 22 37050 S.Maria di<br>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 (%) |
|---------------------|---|----------------------|------------|-----------|-------------|
| Difenacoum          | 3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin | active substance     | 56073-07-5 | 259-978-4 | 0,005       |
| Denatonium benzoate |   | Non-active substance |            |           | 0,001       |

### 2.2. Type(s) of formulation

RB Bait (ready for use)

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### 3. HAZARD AND PRECAUTIONARY STATEMENTS

|                          |  |
|--------------------------|--|
| Hazard statements        | H360D: May damage the unborn child.<br><br>H373: May cause damage to organs (blood) through prolonged or repeated exposure { 1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard: }.  |
| Precautionary statements | P102: Keep out of reach of children.<br><br>P202: Do not handle until all safety precautions have been read and understood.<br><br>P280: Wear protective gloves.<br><br>P308+P313: IF exposed or concerned: Get medical advice.<br><br>P501: Dispose of contents to special waste in accordance with national regulations. |

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. House mice - professional - indoor**

|  |   |
|--|---|
| Product type   | PT14: Rodenticides  |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticides.  |
| Target organism(s) (including development stage)           | Scientific name: <i>Mus musculus</i><br>Common name: house mouse<br>Development stage: Juveniles to adults  |
| Field(s) of use  | indoor use<br><br>Indoor  |
| Application method(s)                                      | Method: bait application<br><br>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations  |
| Application rate(s) and frequency                          | Application rate: 40 g of bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.<br><br>Dilution (%): 0<br><br>Number and timing of application:<br>If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.   |
| Category(ies) of users                                     | industrial ; professional   |
| Pack sizes and packaging material                          | Bait product of 20 g units<br>1,5-3-5-10-20-25 kg<br>Where applicable, package is restricted to separately packed bags with a maximum bag size of 10 kg<br>Packaging material: Plastic composite-triple layer (polyester/PET met/polyethylene)<br><br><b>Type of packaging</b><br><b>Size/Volume of the packaging</b><br><b>Material of the packaging</b><br><b>Type and material of closure(s)</b><br><b>Compatibility of the product with the proposed packaging materials (Yes/No)</b><br>Labelled or printed Bag/Sack<br>1,5-3-5-10-20-25 kg<br>Plastic composite<br>Prefabricated bags or serial production bags, both thermal welded<br>Yes<br><br>Labelled or printed Bag/Sack- with inner plastic liner<br>1,5-3-5-10 kg – max size inner liner 10 kg |

|  |   |
|--|---|
|  | <p>Plastic composite<br/> Prefabricated bags or serial production bags, both thermal welded<br/> Yes</p> <p>Labelled plastic (HDPE) Bucket<br/> 1,5-3-5-10-20-25 kg<br/> Labelled plastic (HDPE) Bucket<br/> Rectangular or truncated cone bucket sealed<br/> Yes</p> <p>Labelled plastic (HDPE) Bucket- with inner plastic liner<br/> 1,5-3-5-10 kg – max size inner liner 10 kg<br/> Labelled plastic (HDPE) Bucket<br/> Rectangular or truncated cone bucket sealed<br/> Yes</p> <p>Labelled or printed Carton sachet with plastic inner liner<br/> 1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/> Carton+plastic composite<br/> Prefabricated bags or serial production bags, both thermal welded<br/> Yes</p> <p>Labelled or printed Cardboard with inner plastic liner<br/> 1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/> Carton+plastic composite<br/> Prefabricated cardboard<br/> Yes</p> |
|--|---|

**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**

Use-specific risk mitigation measures are not necessary when risk mitigation measures, as detailed in the section “General directions for use (professionals)”, are implemented.

**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**

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

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

Use specific instruction for safe disposal of the product and its packaging are not necessary when instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (professionals)”, are implemented.

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

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section “General directions for use (professionals)”, are implemented.

Shelf life: 24 months.

## 4.2. Use description

**Table 2. Rats - professional - indoor**

|  |   |
|--|---|
| Product type   | PT14: Rodenticides  |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticides.  |
| Target organism(s) (including development stage)           | Scientific name: <i>Rattus norvegicus</i><br>Common name: brown rat<br>Development stage: Juveniles to adults<br><br>Scientific name: <i>Rattus rattus</i><br>Common name: roof rat<br>Development stage: Juveniles to adults   |
| Field(s) of use  | indoor use<br><br>Indoor  |
| Application method(s)                                      | Method: bait application<br><br>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations.   |
| Application rate(s) and frequency                          | Application rate: 60-100 g of bait per bait point. If more than one bait point is needed, the minimum distance between bait stations should be of 5 meters.<br><br>Dilution (%): 0<br><br>Number and timing of application:<br>If more than one bait point is needed, the minimum distance between bait stations should be of 5 meters. |

|                                   |   |
|-----------------------------------|---|
|                                   |   |
| Category(ies) of users            | industrial ; professional   |
| Pack sizes and packaging material | <p>Bait product of 20 g units<br/>1,5-3-5-10-20-25 kg<br/>Where applicable, package is restricted to separately packed bags with a maximum bag size of 10 kg<br/>Packaging material: Plastic composite-triple layer (polyester/PET met/polyethylene)</p> <p><b>Type of packaging</b><br/><b>Size/Volume of the packaging</b><br/><b>Material of the packaging</b><br/><b>Type and material of closure(s)</b><br/><b>Compatibility of the product with the proposed packaging materials (Yes/No)</b></p> <p>Labelled or printed Bag/Sack<br/>1,5-3-5-10-20-25 kg<br/>Plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> <p>Labelled or printed Bag/Sack- with inner plastic liner<br/>1,5-3-5-10 kg – max size inner liner 10 kg<br/>Plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> <p>Labelled plastic (HDPE) Bucket<br/>1,5-3-5-10-20-25 kg<br/>Labelled plastic (HDPE) Bucket<br/>Rectangular or truncated cone bucket sealed<br/>Yes</p> <p>Labelled plastic (HDPE) Bucket- with inner plastic liner<br/>1,5-3-5-10 kg – max size inner liner 10 kg<br/>Labelled plastic (HDPE) Bucket<br/>Rectangular or truncated cone bucket sealed<br/>Yes</p> <p>Labelled or printed Carton sachet with plastic inner liner<br/>1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/>Carton+plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> <p>Labelled or printed Cardboard with inner plastic liner<br/>1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/>Carton+plastic composite<br/>Prefabricated cardboard<br/>Yes</p> |



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#### 4.2.1. Use-specific instructions

The bait stations should be visited only 5 to 7 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.

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

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

Use-specific risk mitigation measures are not necessary when risk mitigation measures, as detailed in the section “General directions for use (professionals)”, are implemented.

#### 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

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

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

Use specific instruction for safe disposal of the product and its packaging are not necessary when instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (professionals)”, are implemented.

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

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section “General directions for use (professionals)”, are implemented.

Shelf life: 24 months.

### 4.3. Use description

**Table 3. House mice and rats - professional - 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 |

|                                   |   |
|-----------------------------------|---|
|                                   | <p>Development stage: Juveniles to adults</p> <p>Scientific name: Rattus norvegicus<br/>Common name: brown rat<br/>Development stage: Juveniles to adults</p> <p>Scientific name: Rattus rattus<br/>Common name: roof rat<br/>Development stage: Juveniles to 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: House mouse:40 g of bait per bait point. Rats: 60-100 g of bait per bait point. If more than one bait point is needed, the minimum distance between bait stations should be of 5 meters.</p> <p>Dilution (%): 0</p> <p>Number and timing of application:<br/>If more than one bait point is needed, the minimum distance between bait stations should be of 5 meters.</p>  |
| Category(ies) of users            | <p>industrial ; professional</p>  |
| Pack sizes and packaging material | <p>Bait product of 20 g units<br/>1,5-3-5-10-20-25 kg<br/>Where applicable, package is restricted to separately packed bags with a maximum bag size of 10 kg<br/>Packaging material: Plastic composite-triple layer (polyester/PET met/polyethylene)</p> <p><b>Type of packaging</b><br/><b>Size/Volume of the packaging</b><br/><b>Material of the packaging</b><br/><b>Type and material of closure(s)</b><br/><b>Compatibility of the product with the proposed packaging materials (Yes/No)</b><br/>Labelled or printed Bag/Sack<br/>1,5-3-5-10-20-25 kg<br/>Plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> <p>Labelled or printed Bag/Sack- with inner plastic liner<br/>1,5-3-5-10 kg – max size inner liner 10 kg<br/>Plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> |

|  |  |
|--|--|
|  | <p>Labelled plastic (HDPE) Bucket<br/>1,5-3-5-10-20-25 kg<br/>Labelled plastic (HDPE) Bucket<br/>Rectangular or truncated cone bucket sealed<br/>Yes</p> <p>Labelled plastic (HDPE) Bucket- with inner plastic liner<br/>1,5-3-5-10 kg – max size inner liner 10 kg<br/>Labelled plastic (HDPE) Bucket<br/>Rectangular or truncated cone bucket sealed<br/>Yes</p> <p>Labelled or printed Carton sachet with plastic inner liner<br/>1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/>Carton+plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> <p>Labelled or printed Cardboard with inner plastic liner<br/>1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/>Carton+plastic composite<br/>Prefabricated cardboard<br/>Yes</p> |
|--|--|

#### 4.3.1. 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.

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

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

Do not apply this product directly in the burrows.

#### 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

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.

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

Use specific instruction for safe disposal of the product and its packaging are not necessary when instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (professionals)”, are implemented.

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

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section “General directions for use (professionals)”, are implemented.

Shelf life: 24 months.

**4.4. Use description**

**Table 4. 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)           | <p>Scientific name: <i>Mus musculus</i><br/> Common name: house mouse<br/> Development stage: Juveniles to adults</p> <p>Scientific name: <i>Rattus norvegicus</i><br/> Common name: brown rat<br/> Development stage: Juveniles to adults</p> <p>Scientific name: <i>Rattus rattus</i><br/> Common name: roof rat<br/> Development stage: Juveniles to 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 or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait station.</p>   |
| Application rate(s) and frequency                          | <p>Application rate: Bait products: Rats - High infestation: (60-100) g of bait per baiting point. - Low infestation: (40-60) g of bait per baiting point. Mice: 40 g of bait for baiting point. Permanent baiting 60-100 g of bait per baiting point.</p> <p>Dilution (%): 0</p> <p>Number and timing of application:</p>   |

|                                   |   |
|-----------------------------------|---|
|                                   | <p>Bait products: Rats: High infestation: (60-100) g of bait per baiting point. - Low infestation: (40-60) g of bait per baiting point.</p> <p>Mice: 40 g of bait for baiting point.</p> <p>Permanent baiting 60-100 g of bait per baiting point.</p>   |
| Category(ies) of users            | trained professional  |
| Pack sizes and packaging material | <p>Bait product of 20 g units<br/>1,5-3-5-10-20-25 kg<br/>Where applicable, package is restricted to separately packed bags with a maximum bag size of 10 kg<br/>Packaging material: Plastic composite-triple layer (polyester/PET met/polyethylene)</p> <p><b>Type of packaging</b><br/><b>Size/Volume of the packaging</b><br/><b>Material of the packaging</b><br/><b>Type and material of closure(s)</b><br/><b>Compatibility of the product with the proposed packaging materials (Yes/No)</b></p> <p>Labelled or printed Bag/Sack<br/>1,5-3-5-10-20-25 kg<br/>Plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> <p>Labelled or printed Bag/Sack- with inner plastic liner<br/>1,5-3-5-10 kg – max size inner liner 10 kg<br/>Plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> <p>Labelled plastic (HDPE) Bucket<br/>1,5-3-5-10-20-25 kg<br/>Labelled plastic (HDPE) Bucket<br/>Rectangular or truncated cone bucket sealed<br/>Yes</p> <p>Labelled plastic (HDPE) Bucket- with inner plastic liner<br/>1,5-3-5-10 kg – max size inner liner 10 kg<br/>Labelled plastic (HDPE) Bucket<br/>Rectangular or truncated cone bucket sealed<br/>Yes</p> <p>Labelled or printed Carton sachet with plastic inner liner<br/>1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/>Carton+plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> <p>Labelled or printed Cardboard with inner plastic liner<br/>1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/>Carton+plastic composite</p> |

|  |                                |
|--|--------------------------------|
|  | Prefabricated cardboard<br>Yes |
|--|--------------------------------|

#### 4.4.1. Use-specific instructions

Remove the remaining product at the end of treatment period.

For permanent baiting:

- Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.

- 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

- 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 in pulsed baiting treatments.

- Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.

In case of permanent baiting:

- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.

- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

#### 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

Use specific instruction for safe disposal of the product and its packaging are not necessary when instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (trained professionals)”, are implemented.

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

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section “General directions for use (trained professionals)”, are implemented.

Shelf life: 24 months.

#### 4.5. Use description

**Table 5. 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><br/> Common name: house mouse<br/> Development stage: Juveniles to adults</p> <p>Scientific name: <i>Rattus norvegicus</i><br/> Common name: brown rat<br/> Development stage: Juveniles to adults</p> <p>Scientific name: <i>Rattus rattus</i><br/> Common name: roof rat<br/> Development stage: Juveniles to 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 or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait station.</p>   |
| Application rate(s) and frequency                          | <p>Application rate: Bait products: Rats - High infestation: (60-100) g of bait per baiting point. - Low infestation: (40-60) g of bait per baiting point. Mice: 40 g of bait for baiting point. Permanent baiting 60-100 g of bait per baiting.</p> <p>Dilution (%): 0</p> <p>Number and timing of application:</p> <p>Bait products: Rats: High infestation: (60-100) g of bait per baiting point. - Low infestation: (40-60) g of bait per baiting point.<br/> Mice: 40 g of bait for baiting point.<br/> Permanent baiting 60-100 g of bait per baiting.</p> |

|                                   |   |
|-----------------------------------|---|
| Category(ies) of users            | trained professional  |
| Pack sizes and packaging material | <p>Bait product of 20 g units<br/>1,5-3-5-10-20-25 kg<br/>Where applicable, package is restricted to separately packed bags with a maximum bag size of 10 kg<br/>Packaging material: Plastic composite-triple layer (polyester/PET met/polyethylene)</p> <p><b>Type of packaging</b><br/><b>Size/Volume of the packaging</b><br/><b>Material of the packaging</b><br/><b>Type and material of closure(s)</b><br/><b>Compatibility of the product with the proposed packaging materials (Yes/No)</b></p> <p>Labelled or printed Bag/Sack<br/>1,5-3-5-10-20-25 kg<br/>Plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> <p>Labelled or printed Bag/Sack- with inner plastic liner<br/>1,5-3-5-10 kg – max size inner liner 10 kg<br/>Plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> <p>Labelled plastic (HDPE) Bucket<br/>1,5-3-5-10-20-25 kg<br/>Labelled plastic (HDPE) Bucket<br/>Rectangular or truncated cone bucket sealed<br/>Yes</p> <p>Labelled plastic (HDPE) Bucket- with inner plastic liner<br/>1,5-3-5-10 kg – max size inner liner 10 kg<br/>Labelled plastic (HDPE) Bucket<br/>Rectangular or truncated cone bucket sealed<br/>Yes</p> <p>Labelled or printed Carton sachet with plastic inner liner<br/>1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/>Carton+plastic composite<br/>Prefabricated bags or serial production bags, both thermal welded<br/>Yes</p> <p>Labelled or printed Cardboard with inner plastic liner<br/>1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/>Carton+plastic composite<br/>Prefabricated cardboard<br/>Yes</p> |



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#### **4.5.1. 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.

For permanent baiting:

- Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.

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

For application in covered and protected bait points:

- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
- 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**

- 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.
- Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.
- Do not use the product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

In case of permanent baiting:

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

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

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

Use specific instruction for safe disposal of the product and its packaging are not necessary when instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (trained professionals)”, are implemented.

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

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section “General directions for use (trained professionals)”, are implemented.

Shelf life: 24 months.

#### 4.6. Use description

**Table 6. Rats - trained professionals - outdoor open areas**

|  |  |
|--|--|
| 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 rattus</i><br>Common name: roof rat<br>Development stage: Juveniles to adults<br><br>Scientific name: <i>Rattus norvegicus</i><br>Common name: brown rat<br>Development stage: Juveniles to adults  |
| Field(s) of use  | outdoor use<br><br>Outdoor open areas  |
| Application method(s)                                      | Method: bait application<br><br>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations.   |
| Application rate(s) and frequency                          | Application rate: Bait products: High infestation: (60-100) g of bait per baiting point. - Low infestation: (40-60) g of bait per baiting point. Permanent baiting 60-100 g of bait per baiting point.<br><br>Dilution (%): 0<br><br>Number and timing of application:<br>Bait products: High infestation: (60-100) g of bait per baiting point. - Low infestation: (40-60) g of bait per baiting point. Permanent baiting 60-100 g of bait per baiting point. |
| Category(ies) of users                                     | trained professional   |
| Pack sizes and packaging material                          | Bait product of 20 g units<br>1,5-3-5-10-20-25 kg  |

|  |   |
|--|---|
|  | <p>Where applicable, package is restricted to separately packed bags with a maximum bag size of 10 kg<br/> Packaging material: Plastic composite-triple layer (polyester/PET met/polyethylene)<br/> <b>Type of packaging</b><br/> <b>Size/Volume of the packaging</b><br/> <b>Material of the packaging</b><br/> <b>Type and material of closure(s)</b><br/> <b>Compatibility of the product with the proposed packaging materials (Yes/No)</b><br/> Labelled or printed Bag/Sack<br/> 1,5-3-5-10-20-25 kg<br/> Plastic composite<br/> Prefabricated bags or serial production bags, both thermal welded<br/> Yes</p> <p>Labelled or printed Bag/Sack- with inner plastic liner<br/> 1,5-3-5-10 kg – max size inner liner 10 kg<br/> Plastic composite<br/> Prefabricated bags or serial production bags, both thermal welded<br/> Yes</p> <p>Labelled plastic (HDPE) Bucket<br/> 1,5-3-5-10-20-25 kg<br/> Labelled plastic (HDPE) Bucket<br/> Rectangular or truncated cone bucket sealed<br/> Yes</p> <p>Labelled plastic (HDPE) Bucket- with inner plastic liner<br/> 1,5-3-5-10 kg – max size inner liner 10 kg<br/> Labelled plastic (HDPE) Bucket<br/> Rectangular or truncated cone bucket sealed<br/> Yes</p> <p>Labelled or printed Carton sachet with plastic inner liner<br/> 1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/> Carton+plastic composite<br/> Prefabricated bags or serial production bags, both thermal welded<br/> Yes</p> <p>Labelled or printed Cardboard with inner plastic liner<br/> 1,5-3-5-10 kg – single inner plastic bags of up to 10 kg each<br/> Carton+plastic composite<br/> Prefabricated cardboard<br/> Yes</p> |
|--|---|

#### 4.6.1. 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.

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

For permanent baiting:

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

For application in covered and protected bait points:

- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
- 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**

- 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.
- Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.
- Do not use the product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

In case of permanent baiting:

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

#### **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 surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or 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**

Use specific instruction for safe disposal of the product and its packaging are not necessary when instruction for safe disposal of the product and its packaging, as detailed in the section “General directions for use (trained professionals)”, are implemented.

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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**

Use specific conditions of storage and shelf-life of the product under normal conditions of storage are not necessary when conditions of storage and shelf-life of the product under normal conditions of storage, as detailed in the section “General directions for use (trained professionals)”, are implemented.

Shelf life: 24 months

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

### 5.1. Instructions for use

#### **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 (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Bait stations should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).
- When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Wear protective chemical resistant gloves (rubber) during product handling phase.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Remove the remaining bait or the bait stations at the end of the treatment period.

#### **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.
- 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.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).

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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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- 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 (rubber) during product handling phase.
  - 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.
  - Remove the remaining bait or the bait stations at the end of the treatment period.

## **5.2. Risk mitigation measures**

### **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.
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- The product information (i.e. label and/or leaflet) shall clearly show that: the product shall not be supplied to the general public (e.g. "for professionals only"); the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only"); users shall properly label bait stations with the information referred to in section 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.
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment unless authorised for permanent treatments.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.

- 
- Dispose dead rodents in accordance with local requirements.

### **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.

Contact a veterinary surgeon in case of ingestion by a pet.

- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance" and "in case of incident, call a poison centre".

- 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.

### **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: 24 months.



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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.