

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Bromadiolone Fresh Bait

Product type(s)

PT14: Rodenticides

Authorisation number: 2024-05-14-B01

R4BP asset number: MT-0032710-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

| | |
|---------------|------------------------------------|
| Trade name(s) | Protect PRO rodenticide fresh bait |
|---------------|------------------------------------|

1.2. Authorisation holder

| | | |
|--|-----------------|---|
| Name and address of the authorisation holder | Name | Bábolna Bioenvironmental Centre Private Limited Company |
| | Address | Szállás u. 6. H-1107 Budapest Hungary |
| Authorisation number | 2024-05-14-B01 | |
| <i>R4BP asset number</i> | MT-0032710-0000 | |
| Date of the authorisation | 14/05/2024 | |
| Expiry date of the authorisation | 31/12/2024 | |

1.3. Manufacturer(s) of the product

| | |
|---------------------------------|--------------------------------------|
| Name of manufacturer | Babolna Bio Plc |
| Address of manufacturer | Szállás utca 6 1107 Budapest Hungary |
| Location of manufacturing sites | |

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

| | |
|---------------------------------|---|
| Active substance | Bromadiolone |
| Name of manufacturer | Dr Tezza |
| Address of manufacturer | Via Tre Ponti 37050 S. Maria di Zevio Italy |
| Location of manufacturing sites | Dr Tezza site 1 Via Tre Ponti 37050 S. Maria di Zevio Italy |

2. PRODUCT COMPOSITION AND FORMULATION

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

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--------------|---|------------------|------------|-----------|-------------|
| Bromadiolone | 3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one | active substance | 28772-56-7 | 249-205-9 | 0,005 |

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

| | |
|--------------------------|--|
| Hazard statements | H360D: May damage the unborn child. H372: Causes damage to organs blood through prolonged or repeated exposure .. |
| Precautionary statements | P201: Obtain special instructions before use. P260: Do not breathe dust. P280: Wear protective gloves. P308+P313: IF exposed or concerned: Get medical advice. P405: Store locked up. P501: Dispose of contents to in accordance with local requirements. |

4. AUTHORISED USE(S)

4.1. Use description

Table 1. House mice – professionals – indoor

| | |
|--|---|
| Product type | PT14: Rodenticides |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticide products. |
| Target organism(s) (including development stage) | Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: - juveniles and adults |
| Field(s) of use | indoor use Indoor |
| Application method(s) | Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations (rodenticide paste in filterpaper sachets) |
| Application rate(s) and frequency | Application rate: - Dilution (%): - Number and timing of application: <u>On the outer packaging of the plastic mouse box (Protect Boxer):</u> 1 box every 10 meters (for low infestation), 1 box every 5 meters (for high infestation). <u>In bait station:</u> 40 g of bait every 10 meters (for low infestation), 40 g of bait every 5 meter (for high infestation). |
| Category(ies) of users | professional |
| Pack sizes and packaging material | - <u>Filter paper bags containing 10 grams of bait:</u> in a plastic bag - 0.1; 0.2; 0.25; 0.3 kg in a plastic bag placed in a paper box - 0.25; 0.3; 0.4; 0.5; 1 kg in a plastic mouse box placed in paper box - 2 x 4 x 10 g feeding boxes / paper box in a plastic bucket - 1, 5 and 10 kg in a plastic bag, cardboard box or paper box - 25 kg <u>Filter paper bags containing 20 grams of bait:</u> in a plastic bag, cardboard box or paper box - 25 kg |

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.

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

Remove the remaining product at the end of treatment period.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

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

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

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

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

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4.2. Use description

Table 2. Rats – professionals – indoor

| | |
|--|---|
| Product type | PT14: Rodenticides |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticide products. |
| Target organism(s) (including development stage) | Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: - juveniles and adults |
| Field(s) of use | indoor use Indoor |
| Application method(s) | Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations (rodenticide paste in filterpaper sachets) |

| | |
|-----------------------------------|---|
| Application rate(s) and frequency | Application rate: - Dilution (%): - Number and timing of application: <u>In bait station:</u> 120 g of bait (max. 200 g) every 10 meters (for low infestation), 120 g of bait (max. 200 g) every 5 meters (for high infestation). |
| Category(ies) of users | professional |
| Pack sizes and packaging material | - <u>Filter paper bags containing 10 grams of bait:</u> in a plastic bag - 0.1; 0.2; 0.25; 0.3 kg in a plastic bag placed in a paper box - 0.25; 0.3; 0.4; 0.5; 1 kg in a plastic mouse box placed in paper box - 2 x 4 x 10 g feeding boxes / paper box in a plastic bucket - 1, 5 and 10 kg in a plastic bag, cardboard box or paper box - 25 kg <u>Filter paper bags containing 20 grams of bait:</u> in a plastic bag, cardboard box or paper box - 25 kg |

4.2.1. Use-specific instructions

The bait stations should be visited at least every 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.

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

Re-fill bait when necessary.

Remove the remaining product at the end of treatment period.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

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

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

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

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4.3. Use description

Table 3. House mouse and rat – professional – around buildings

| | |
|--|--|
| Product type | PT14: Rodenticides |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticide products. |
| Target organism(s) (including development stage) | <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: - juveniles and adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: - juveniles and adults</p> |
| 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: -</p> <p>Dilution (%): -</p> <p>Number and timing of application:</p> <p><u>On the outer packaging of the plastic mouse box (Protect Boxer):</u></p> <p>1 box every 10 meters (for low infestation), 1 box every 5 meters (for high infestation).</p> <p><u>In bait station:</u> <u>for mice:</u></p> <p>40 g of bait every 10 meters (for low infestation), 40-50 g of bait every 5 meter (for high infestation).</p> <p><u>for rats:</u> 120 g of bait (max. 200 g) every 10 meters (for low infestation), 120 g of bait (max. 200 g) every 5 meters (for high infestation).</p> |
| Category(ies) of users | professional |
| Pack sizes and packaging material | <p>-</p> <p><u>Filter paper bags containing 10 grams of bait:</u></p> |

| | |
|--|--|
| | <p>in a plastic bag - 0.1; 0.2; 0.25; 0.3 kg</p> <p>in a plastic bag placed in a paper box - 0.25; 0.3; 0.4; 0.5; 1 kg</p> <p>in a plastic mouse box placed in paper box - 2 x 4 x 10 g feeding boxes / paper box</p> <p>in a plastic bucket - 1, 5 and 10 kg</p> <p>in a plastic bag, cardboard box or paper box - 25 kg</p> <p><u>Filter paper bags containing 20 grams of bait:</u></p> <p>in a plastic bag, cardboard box or paper box - 25 kg</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 at least every 2 to 3 days (for mice) and only 5 to 7 days after the beginning of the treatment (for rats) and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

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

Remove the remaining product at the end of treatment period.

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

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

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4.4. Use description

Table 4. House mice and rats - trained professionals - indoor

| | |
|--------------|--------------------|
| Product type | PT14: Rodenticides |
|--------------|--------------------|

| | |
|--|--|
| Where relevant, an exact description of the authorised use | Not relevant for rodenticide products. |
| Target organism(s) (including development stage) | <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: - juveniles and adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: - juveniles and adults</p> |
| 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 stations.</p> |
| Application rate(s) and frequency | <p>Application rate: -</p> <p>Dilution (%): -</p> <p>Number and timing of application:</p> <p><u>On the outer packaging of the plastic mouse box (Protect Boxer):</u></p> <p>1 box every 10 meters (for low infestation), 1 box every 5 meters (for high infestation).</p> <p><u>In bait station:</u> <u>for mice:</u></p> <p>40 g of bait every 10 meters (for low infestation), 40-50 g of bait every 5 meter (for high infestation).</p> <p><u>for rats:</u> 120 g of bait (max. 200 g) every 10 meters (for low infestation), 120 g of bait (max. 200 g) every 5 meters (for high infestation).</p> <p><u>permanent baiting:</u></p> <p>40 - 200 g of bait per baiting point.</p> |
| Category(ies) of users | trained professional |
| Pack sizes and packaging material | <p>–</p> <p><u>Filter paper bags containing 10 grams of bait:</u> in a plastic bag - 0.1; 0.2; 0.25; 0.3 kg in a plastic bag placed in a paper box - 0.25; 0.3; 0.4; 0.5; 1 kg in a plastic mouse box placed in paper box - 2 x 4 x 10 g feeding boxes / paper box in a plastic bucket - 1, 5 and 10 kg in a plastic bag, cardboard box or paper box - 25 kg</p> <p><u>Filter paper bags containing 20 grams of bait:</u></p> |

| | |
|--|--|
| | in a plastic bag, cardboard box or paper box - 25 kg |
|--|--|

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

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 reinvansion.

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 reinvansion 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 reinvansion 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 system, ensure that bait contact with water is avoided.

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

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

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4.5. Use description

Table 5. 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 rodenticide products. |
| Target organism(s) (including development stage) | <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: - juveniles and adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: - juveniles and adults</p> |
| 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 stations.</p> |
| Application rate(s) and frequency | <p>Application rate: -</p> <p>Dilution (%): -</p> <p>Number and timing of application:</p> <p><u>On the outer packaging of the plastic mouse box (Protect Boxer):</u></p> <p>1 box every 10 meters (for low infestation), 1 box every 5 meters (for high infestation).</p> <p><u>In bait station:</u></p> <p><u>for mice:</u></p> <p>40 g of bait every 10 meters (for low infestation), 40-50 g of bait every 5 meter (for high infestation).</p> <p><u>for rats:</u></p> <p>120 g of bait (max. 200 g) every 10 meters (for low infestation), 120 g of bait (max. 200 g) every 5 meters (for high infestation).</p> <p><u>permanent baiting:</u></p> <p>40 - 200 g of bait per baiting point.</p> |
| Category(ies) of users | trained professional |
| Pack sizes and packaging material | <p>–</p> <p><u>Filter paper bags containing 10 grams of bait:</u></p> <p>in a plastic bag - 0.1; 0.2; 0.25; 0.3 kg</p> <p>in a plastic bag placed in a paper box - 0.25; 0.3; 0.4; 0.5; 1 kg</p> <p>in a plastic mouse box placed in paper box - 2 x 4 x 10 g feeding boxes / paper box</p> <p>in a plastic bucket - 1, 5 and 10 kg</p> |

| | |
|--|--|
| | <p>in a plastic bag, cardboard box or paper box - 25 kg</p> <p><u>Filter paper bags containing 20 grams of bait:</u></p> <p>in a plastic bag, cardboard box or paper box - 25 kg</p> |
|--|--|

4.5.1. 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.

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

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.

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

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

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

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.). 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). 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

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. Instructions for use that are "bait-specific": - Bait in sachets: Do not open the sachets containing the bait.

5.2. Risk mitigation measures

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 baiting 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.

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

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(s)" 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.

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: 24 months

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.

The label includes:

PROTECT® PRO rágcsálóirtó pép

Active substance: 0.005% bromadiolone

II. category biocide

Authorisation holder: Bábolna Bio Ltd. (Budapest, Hungary)

Biocid license number: HU-2017-SP-14-00190-0000

as well as the following sections of this document:

2.2, 3, 4, (excluding packaging), and 5, 6 parts.

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Plastic rod boxes shall bear the following text:

PROTECT® PRO rágcsálóirtó pép

Active substance: 0.005% bromadiolone

Antidote: K1 vitamine

Authorisation holder: Bábolna Bio Ltd. (Budapest, Hungary)

Biocid license number: HU-2017-SP-14-00190-0000

The label of filter papers includes:

PROTECT® PRO rágcsálóirtó pép

Active substance: 0.005% bromadiolone

Antidote: K1 vitamine