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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

PROTECT REVOLUTION rágcsálóirtó granulátum

Product type(s)

PT14: Rodenticides

Authorisation number: HU-2014-SP-14-00120-0000

R4BP asset number: HU-0007663-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	PROTECT REVOLUTION rágcsálóirtó granulátum Protect Revolution rodenticide pellet
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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	HU-2014-SP-14-00120-0000	
<i>R4BP asset number</i>	HU-0007663-0000	
Date of the authorisation	11/06/2013	
Expiry date of the authorisation	31/12/2026	

1.3. Manufacturer(s) of the product

Name of manufacturer	Babolna Bio Ltd.
Address of manufacturer	Szállás utca 6 1107 Budapest Hungary
Location of manufacturing sites	Köves János utca 1-3. 2943 Bábolna Hungary

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

Active substance	Bromadiolone
Name of manufacturer	Babolna Bio Limited (Member of the Bromadiolone Task Force)
Address of manufacturer	Dr Tezza S.r.l. - Via Tre Ponti 37050 S. Maria di Zevio Italy
Location of manufacturing sites	PM Tezza S.r.l. - 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	0,0027

2.2. Type(s) of formulation

RB - Bait (ready for use): rodenticide pellet

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H373: May cause damage to organs . through prolonged or repeated exposure (blood).
Precautionary statements	P102: Keep out of reach of children. P202: Do not handle until all safety precautions have been read and understood. P280: Wear protective gloves. P280: Wear protective clothing. 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 and rats – general public – 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 Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: juveniles and adults
Field(s) of use	indoor use indoor
Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait station.
Application rate(s) and frequency	Application rate: - Dilution (%): - Number and timing of application: Against mice: Tray: 1 tray containing 75g or 90 g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters. Filter paper or plastic sachet: Up to 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters. Against rats: Tray: 1 tray containing 150g bait or 2 trays containing 75g, 90 or 125 g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation). Filter paper or plastic sachet: 150 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).

Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<p>plastic tray containing 75, 90, 125, 150 g bait covered by filter paper, in paper box or plastic sachet. 1-2 trays in paper box or plastic sachet. Up to 150 g.</p> <p>filter paper sachets containing 10, 20, 25 or 50 g bait in carton box. Up to 150 g</p> <p>20 or 25 g filter paper sachets, 2 sachets in plastic baiting box. 1 or 2 boxes in paper box.</p> <p>plastic sachet or aroma permeable sachet containing 100 or 150 g bait in carton paper box. Up to 150 g</p> <p>plastic sachet containing 100 or 150 g bait.</p>

4.1.1. Use-specific instructions

When used against mice:

- 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.

When used against rats:

- 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.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

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

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

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

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4.2. Use description

Table 2. Rats – general public – 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)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: juveniles and adults
Field(s) of use	outdoor use outdoor around buildings
Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait station.
Application rate(s) and frequency	Application rate: - Dilution (%): - Number and timing of application: Tray: 1 tray containing 150g bait or 2 trays containing 75g, 90g or 125g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation). Filter paper or plastic sachet: 150 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	plastic tray containing 75, 90, 125, 150 g bait covered by filter paper, in paper box or plastic sachet. 1-2 trays in paper box or plastic sachet. Up to 150 g. plastic tray containing 75 or 90 g bait covered by filter paper + 50 g appetizing gel with aluminium foil covering, in paper box. 1-2 trays in paper box. Up to 150 g. filter paper sachets containing 10, 20, 25 or 50 g bait in carton box. Up to 150 g 20 or 25 g filter paper sachets, 2 sachets in plastic baiting box. 1 or 2 boxes in paper box. plastic sachet or aroma permeable sachet containing 100 or 150 g bait in carton paper box. Up to 150 g plastic sachet containing 100 or 150 g bait.

4.2.1. 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.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

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

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

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

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4.3. Use description

Table 3. 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)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles and adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: juveniles and adults
Field(s) of use	indoor use

	indoor
Application method(s)	Method: bait application Detailed description: 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: - Dilution (%): - Number and timing of application: <u>For mice</u> Bulk: Up to 100 g of bait per baiting point. Tray: 1 tray containing 75g or 90 g bait per baiting point. Filter paper sachet: Up to 100 g of bait per baiting point <u>For rats:</u> Bulk: Up to 250 g of bait per baiting point. Tray: 1 tray containing 150g or 175g bait or 2 trays containing 75g, 90g or 125g bait per baiting point. Filter paper sachet: Up to 250 g of bait per baiting point. — - <u>Permanent baiting:</u> Up to 250 g of bait per baiting point.
Category(ies) of users	trained professional
Pack sizes and packaging material	plastic tray containing 75, 90, 125, 150 or 175 g bait covered by filter paper, in paper box. Up to 20 kg plastic tray containing 75 or 90 g bait with filter paper covering + 50 g appetizing gel with aluminium foil covering, in paper box. Up to 20 kg filter paper sachets containing 20, 25 or 50 g bait in carton box. Up to 20 kg bulk in plastic bucket. Up to 20 kg with separate inner packages of maximum 10 kg in plastic bags bulk in paper barrel. Up to 30 kg with separate inner packages of maximum 10 kg in plastic bags bulk in plastic sachet in carton box. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags bulk in paper bag. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags

4.3.1. Use-specific instructions

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.

4.3.2. Use-specific risk mitigation measures

4.3.3. 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 apply this product directly in the burrows .

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.

4.3.4. 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 points close to water drainage system, 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 – 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> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: juveniles and adults</p>
Field(s) of use	<p>outdoor use</p> <p>outdoor around buildings</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations 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>For mice</u> Bulk: Up to 100 g of bait per baiting point. Tray: 1 tray containing 75g or 90 g bait per baiting point. Filter paper sachet: Up to 100 g of bait per baiting point</p> <p><u>For rats:</u> Bulk: Up to 250g of bait per baiting point. Tray: 1 tray containing 150g or 175g bait or 2 trays containing 75g, 90g or 125g bait per baiting point. Filter paper sachet: Up to 250 g of bait per baiting point.</p> <p><u>Permanent baiting:</u> Up to 250 g of bait per baiting point.</p>
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>plastic tray containing 75, 90, 125, 150 or 175 g bait covered by filter paper, in paper box. Up to 20 kg</p> <p>filter paper sachets containing 20, 25 or 50 g bait in carton box. Up to 20 kg</p> <p>bulk in plastic bucket. Up to 20 kg with separate inner packages of maximum 10 kg in plastic bags</p> <p>bulk in paper barrel. Up to 30 kg with separate inner packages of maximum 10 kg in plastic bags</p> <p>bulk in plastic sachet in carton box. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags</p> <p>bulk in paper bag. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags</p>

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4.4.1. 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.

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 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 apply this product directly in the burrows.

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.

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

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

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

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5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

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.
- 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.

Trained professional:

- 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 (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.
- 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 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

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

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.

- Instructions for use that are "bait-specific":

- Bait in filter paper sachets: Do not open the sachets containing the bait.
- Bait in trays: Do not open the cover of the trays containing the bait.
- Trays with appetizing gel: Remove the grey aluminium foil before application while leaving the white foil on the tray without opening it. The white foil being aroma permeable, allows the rodents to find the rodenticide. It also increases the safety of the application since no exposure occurs to the rodenticide. Should the appetizing gel dry up, pour on approx. 50 ml of water. When the water is absorbed, the gel recovers its initial consistence. Take care to keep the granules away from water. Rehydrate gel only when the protect film covering pellets is intact. The appetizing gel is a non-hazardous mixture according to manufacturer and in compliance with Reg. 1272/2008/EC.

5.2. Risk mitigation measures

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.

Trained professional:

- 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 [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

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

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- 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, always check for and remove contact lenses, rinse eyes for several minutes with eyes-rinse liquid or water
 - 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 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.

Biocid number of expert report: 38822-1/2020/KBKHF

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The label includes:

PROTECT REVOLUTION rágcsálóirtó granulátum

Active substance: 0.0027% bromadiolone

III. category pesticide

Authorisation holder: Babolna Bio Ltd. (Hungary)

Biocid license number:

as well as the following sections of this document, depending on the scope of users:

for general public: 2.2, 3, 4.1-4.3. (excluding packaging) and 5, 6 parts

for trained professional users: 2.2, 3, 4.4-4.5. (excluding packaging), and 5, 6 parts.

In addition the label on filter paper or on plastic bag containing the rodenticide include:

PROTECT REVOLUTION rágcsálóirtó granulátum

Active substance: 0.0027% bromadiolone

Antidote: K1-vitamine