

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Bromadiolone Wax Block (compressed)

Product type(s)

PT14: Rodenticides

Authorisation number: UST201706-184

R4BP asset number: IS-0009390-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Bromadiolone Wax Block (compressed) Rode holræsavaxkubbar
---------------	--

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Streymi heildverslun ehf.
	Address	Goðanesi 4 603 Akureyri Iceland
Authorisation number		UST201706-184
<i>R4BP asset number</i>		IS-0009390-0000
Date of the authorisation		16/10/2012
Expiry date of the authorisation		31/12/2026

1.3. Manufacturer(s) of the product

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

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	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 { 1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard: }.
Precautionary statements	P201: Obtain special instructions before use. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. 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. rat - professionals - indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults
Field(s) of use	indoor use Indoor
Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Application rate: 75-100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters (for high levels of infestation) to 10 meters (for low levels of infestation). Dilution (%): - Number and timing of application: -
Category(ies) of users	professional
Pack sizes and packaging material	75, 100, 120 or 200 g blocks in plastic wrapping in carton box Up to 25 kg packaging material: polyethylene (PE) + carton paper

4.1.1. 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.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

-

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

-

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

-

4.2. Use description

Table 2. rat - professionals - 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>Rattus norvegicus</i> Common name: brown 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 stations.
Application rate(s) and frequency	Application rate: 75-100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters (for high levels of infestation) to 10 meters (for low levels of infestation). Dilution (%): -

	Number and timing of application: -
Category(ies) of users	professional
Pack sizes and packaging material	75, 100, 120 or 200 g blocks in plastic wrapping in carton box Up to 25 kg packaging material: polyethylene (PE) + carton paper

4.2.1. 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 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.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

-

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

-

4.3. Use description

Table 3. rat - trained professionals - indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: <i>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 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: 75-100 g of bait per baiting point. Dilution (%): - Number and timing of application: -
Category(ies) of users	trained professional
Pack sizes and packaging material	75, 100, 120 or 200 g blocks in plastic wrapping in carton box Up to 25 kg packaging material: polyethylene (PE) + carton paper

4.3.1. 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.

4.3.2. 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 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

-

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

-

4.4. Use description

Table 4. rat - trained professionals - outdoor around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown 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 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: 75-100 g of bait per baiting point. Dilution (%): - Number and timing of application: -
Category(ies) of users	trained professional
Pack sizes and packaging material	75, 100, 120 or 200 g blocks in plastic wrapping in carton box Up to 25 kg packaging material: polyethylene (PE) + carton paper

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.

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.

4.4.2. 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 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

-

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

-

4.5. Use description

Table 5. rat - trained professionals - outdoor open areas & waste dumps

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults
Field(s) of use	outdoor use Outdoor: open areas and waste dumps
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: 75-100 g of bait per baiting point. Dilution (%): - Number and timing of application: -
Category(ies) of users	trained professional
Pack sizes and packaging material	75, 100, 120 or 200 g blocks in plastic wrapping in carton box

	Up to 25 kg packaging material: polyethylene (PE) + carton paper
--	---

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
- 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

-

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

-

4.6. Use description

Table 6. rat - trained professionals - sewer

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles and adults
Field(s) of use	Other Sewers
Application method(s)	Method: bait application Detailed description: - Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water. Covered and protected baiting points are also authorised 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: 75-200 g of bait per manhole Dilution (%): - Number and timing of application: -
Category(ies) of users	trained professional
Pack sizes and packaging material	75, 100, 120 or 200 g blocks in plastic wrapping in carton box Up to 25 kg packaging material: polyethylene (PE) + carton paper

4.6.1. Use-specific instructions

- Baits must be applied in a way so that they do not come into contact with water and are not washed away.
- 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

- Place baits only in sewer systems which are connected to the sewage treatment plant.
- Do not use the product in pulsed baiting treatments.

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

-

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

-

4.6.6. 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.

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. "**aðeins til notkunar í atvinnuskyni**").
- 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.

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

-
- 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, always check for and remove contact lenses, rinse eyes with eyes-rinse liquid or water, keep eye lids open for 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: "**Má ekki færa eða opna**"; "**inniheldur nagdýraeitur**"; "product name or authorisation number"; "active substance(s)" and "**ef atvik kemur upp, hringið í Eitrunarmiðstöð s. 543 2222 eða 112**".

- 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 it in the original, sealed pack, protected from light in a dry, cool, well-ventilated, closed place. Store in places prevented from the access of children, birds, pets and farm animals.

Shelf life: 2 years after the date of production.

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.

The signal word, hazard- and precautionary statements shall be in Icelandic on the product label.

Signal word:

Hætta

Hazard statements:

H360D Getur haft skaðleg áhrif á börn í móðurkviði.

H372 Skaðar líffæri (blóð) við langvinn eða endurtekin váhrif.

Precautionary statements:

P201 Aflið sérstakra leiðbeininga fyrir notkun.

P264 Þvoið hendur vandlega eftir meðhöndlun.

P270 Neytið ekki matar, drykkjar eða tóbaks við notkun þessarar vöru.

P280 Notið hlífðarhanska.

P308+P313 EF um váhrif eða hugsanleg váhrif er að ræða: Leitið lækni.

P405 Geymist á læstum stað.

P501 Fargið innihaldi í samræmi við staðbundnar reglur.